Regulation Number: 900 KAR 5:020
Edition Date: ~~May~~ November ~~2011~~2012

~~2011~~ 2012 Update to the 2010 – 2012 STATE HEALTH PLAN

(~~May~~ November ~~2011~~2012)

CERTIFICATE OF NEED REVIEW STANDARDS

Prepared by:

Kentucky Cabinet for Health and Family Services

Table of Contents

Purpose, Authority and Technical Notes

Purpose

The purpose of this document, which shall be referred to as the 2010 - 2012 State Health Plan ("Plan"), is to set forth the review criteria that shall be used when reviewing applications for certificates of need for consistency with plans pursuant to KRS 216B.040; and for determining whether a substantial change to a health service has occurred pursuant to KRS 216B.015(28) and KRS 216B.061(1)(d).

Authority

KRS 216B.015(27) defines the "State Health Plan" to mean the document prepared triennially, updated annually and approved by the governor.

KRS 216B.040(2)(a)2, requires the Cabinet for Health and Family Services ("Cabinet") to establish criteria for the issuance and denial of certificates of need and limits such review to five considerations. The first such consideration is "consistency with plans" which requires that "each proposal approved by the Cabinet shall be consistent with the State Health Plan, and shall be subject to biennial budget authorizations and limitations, and with consideration given to the proposal's impact on health care costs in the Commonwealth."

Technical Notes

1. Unless otherwise noted, Area Development Districts ("ADD's") are defined by KRS 147A.050 and are the geographic areas for reviewing all applications for certificate of need.

2. Where applicable, an applicant shall set forth its plan for care of patients without private insurance coverage and its plan for care of medically underserved populations within the applicant's proposed service area.

3. In reviewing applications for certificates of need, the latest published version of the Cabinet *Inventory of Kentucky Health Facilities, Health Services, and Major Medical Equipment* and published utilization reports shall be used. Additions of equipment or services by existing licensed facilities which do not require certificate of need approval shall be included in the inventory of existing and newly approved facilities and services when such facilities and services become operational. Facilities which make such additions shall notify the Office of Health Policy within ten (10) days of such addition by completing ~~Form #10A~~OHP-Form 10A, Notice of Addition or Establishment of a Health Service or Equipment, incorporated by reference in 900 KAR 6:055.

4. All Magnetic Resonance Imaging Units in operation within the Commonwealth shall be disclosed to the Cabinet for Health and Family Services for publication in the *Kentucky Annual Magnetic Resonance Imaging Services Report*. Health Services that are provided

in private offices and clinics of physicians, dentists, and other practitioners of the healing arts which are exempt from certificate of need requirements pursuant to KRS 216B.020(2)(a) shall not be included in the Cabinet's *Inventory of Health Facilities, Health Services, and Major Medical Equipment.* In addition, utilization of such services shall not be considered when determining consistency with this Plan but may be used by the applicant to address review criteria required by 900 KAR 6:070, Section 2(2) through (6).

5. Facilities owned or operated by the Commonwealth of Kentucky shall not be included in the inventory or need calculations of licensed or approved acute, psychiatric, or long-term care beds.

6. All certificate of need decisions shall be made using that version of the Plan in effect on the date of the decision, regardless of when the letter of intent or application was filed, or public hearing held.

7. Applications which have been granted nonsubstantive review status shall not be reviewed for consistency with this Plan.

8. The *Inventory of Kentucky Health Facilities, Health Services, and Major Medical Equipment* and the *Kentucky Annual Magnetic Resonance Imaging Services Report* shall be available from the Office of Health Policy at 275 East Main St., Frankfort, Kentucky, 40621, (502) 564-9589 or (502) 564-9592 and at Web Site: http://chfs.ky.gov/ohp/con.

9. If more than one provider applies for certificate of need approval to establish or expand a healthcare facility or service in the same service area, a comparative hearing on the applications may be held.

10. All population estimates or projections for use with any criteria contained within this Plan shall pertain only to the population within the Commonwealth of Kentucky and shall be obtained from the Kentucky State Data Center each ~~January~~ May 1st. This data shall be available from the Office of Health Policy at 275 East Main St., Frankfort, Kentucky, 40621, (502) 564-9589 or (502) 564-9592 and at Web Site: http://chfs.ky.gov/ohp/con.

11. Applications to establish a service utilizing a hybrid diagnostic unit such as PET/CT Scanner or PET/MRI Scanner must document consistency with all applicable individual review criteria contained within this Plan.

12. For the purposes of this plan, the terms "child", "adolescent" and "pediatric" refer to individuals younger than eighteen (18) years of age. An "adult" is an individual eighteen (18) years of age or older and a "geriatric" patient is sixty five (65) years of age or older.

I. Acute Care

For purposes of this Plan, "Acute care" is defined as those medical and/or surgical services provided by an acute care hospital for the diagnosis and/or the immediate and continuous treatment for more than twenty-four (24) hours to individuals suffering from illness, disease or injury.

A. Acute Care Hospital

Definitions

An "Acute Care Hospital" is defined as a facility providing medical and/or surgical services to all individuals that seek care and treatment, regardless of the individual's ability to pay for such services. Acute care hospitals are capable of providing care on an immediate and emergent basis through an established Emergency Department as well as continuous treatment on its premises for more than twenty-four (24) hours. Such facilities are licensed by the Kentucky Office of Inspector General, Division of Health Care Facilities pursuant to 902 KAR 20:016. For the purposes of this section, the term acute care hospital shall not include critical access hospitals which are licensed by the Kentucky Office of Inspector General pursuant to 906 KAR 1:110.

A "Specialty Hospital" is defined as a facility offering limited, specialized medical and/or surgical services. Such facilities are distinguishable from acute care hospitals because they do not provide an Emergency Department on a twenty-four (24) hour basis and/or are incapable of satisfying one or more requirements for licensure pursuant to 902 KAR 20:016.

With regard to acute care hospitals, the "Planning Area" shall be comprised of the county of the proposed facility and all contiguous counties.

The "Adjusted Revenue" is defined as the case mix adjusted net revenue per adjusted admission. The applicant shall utilize the most recent Medicare Cost Report data to calculate the following formula:

Adjusted Revenue = (Total Net Revenue/ADJ Admissions)/MCMI

Where:

Total Net Revenue = TGR - Contractual/Charity Allowances

TGR = Inpatient Gross Revenue + Outpatient Gross Revenue

IGR = Inpatient Gross Revenue

OGR = Outpatient Gross Revenue

ADJ Admissions = (TGR/IGR) * IA

IA = Inpatient Admissions

MCMI = Medicare Case Mix Index

Review Criteria

An application to establish a new acute care hospital shall be consistent with this Plan if the following criteria are met:

1. The applicant shall demonstrate that sufficient need for the proposed facility exists and that the establishment of the proposed facility would not result in the unnecessary duplication of services by documenting one or more of the following:

    a. The overall occupancy of existing acute care beds in existing licensed acute care hospitals located in the planning area exceeds eighty (80) percent according to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*;

    b. The adjusted revenue of each licensed acute care hospital located within the planning area exceeded one-hundred and fifty (150) percent of the state mean adjusted revenue, for acute care hospitals, during each of the previous three (3) fiscal years; or

    c. All licensed acute care hospitals located within the planning area have experienced one or more of the following:

        i. Final termination of their Medicare or Medicaid provider agreement;

        ii. Final revocation of the hospital license issued by the Cabinet for Health and Family Services, Office of Inspector General; or

        iii. Final revocation of their hospital accreditation by the Joint Commission on Accreditation of Healthcare Organizations.

2. The applicant shall demonstrate the ability to provide safe, efficient and quality care and treatment to all individuals seeking medical and/or surgical services by documenting the following:

    a. The individual(s) responsible for the operation, management and day-to-day control of the proposed facility has a documented history of providing healthcare services in conformity with federal and state standards. Moreover, no such individual has had any license or certification denied, revoked or involuntarily terminated, or has been excluded from participation in Medicare or Medicaid, or been convicted of fraud or abuse of these programs;

b. Written policies and/or protocols that implement measures to assure quality control with respect to the life, health and safety of individuals seeking care and treatment at the proposed facility. These include documented plans of action that not only serve to prevent, but also identify, diagnose, control and treat injuries or problems including, but not limited to, the following:

i. Acute myocardial infarctions sustained after arrival at the proposed facility;

ii. Hospital-acquired infections;

iii. Medication errors;

iv. Hospital-acquired pneumonia;

v. Death in low mortality Diagnosis Related Groups;

vi. Re-admittance within twenty-four (24) hours of discharge;

vii. Foreign objects not removed during surgical procedures;

viii. Post-operative respiratory failure;

ix. Post-operative sepsis;

x. Decubitus ulcers;

xi. Adverse reactions to the administration of medications and/or transfusions; and

xii. Injuries sustained as a result of falls on the proposed facility's premises;

c. Written policies and/or protocols that implement measures to assure the proper use and utilization of all equipment to be maintained on the proposed facility's property which would be used in the care and treatment of potential patients;

d. The applicant must identify the licensed physicians that would provide care and treatment to patients at the proposed facility. The applicant must further demonstrate that the retention of such individuals would not adversely affect the clinical care and treatment offered at other licensed acute care hospitals located within the planning area; and

e. The applicant must demonstrate that it has identified and would retain trained, experienced or licensed personnel to provide efficient and effective clinical care and treatment to the proposed facility's patients. The applicant must further

demonstrate that the retention of such individuals would not adversely affect the clinical care and treatment offered at other licensed acute care hospitals located within the planning area.

3. The applicant shall demonstrate the ability to provide cost-effective services by documenting the following:

   a. The proposed facility's payor mix would be comparable to all other licensed acute care hospitals located within the planning area; and

   b. A written business plan through which the economic performance and financial strength of the proposed facility would be comparable to the existing acute care hospitals located within the planning area. Specifically, the applicant must document that its adjusted revenue would not exceed one-hundred and fifty (150) percent of the state mean adjusted revenue.

4. The applicant shall demonstrate that the proposed facility would increase access to twenty-four (24) hour acute care and treatment by documenting the following:

   a. The proposed facility would provide care on an immediate and emergent basis through an established Emergency Department; and

   b. The proposed facility would provide emergency services to all individuals that seek care and treatment there, regardless of the individual's ability to pay for such services.

5. The applicant shall demonstrate both its intention as well as its ability to provide the same or substantially similar clinical services offered by the existing acute care hospitals located within the planning area.

6. The maximum number of acute care beds that may be approved for the purpose of constructing or establishing a new acute care hospital shall be based on volume projected five (5) years from the filing of the application. Approval will be based on the higher of:

   a. The applicant's credible forecast of future utilization; or

   b. A regression analysis projection of patient day trends over a five (5) year timeframe.

7. The applicant shall obtain certificate of need approval for each service it proposes to offer by satisfying the review criteria for each service set forth within this Plan.

8. No application for a specialty hospital shall be consistent with this Plan.

B. Acute Care Beds

Definition

An "acute care bed" is defined as a hospital bed licensed by the Cabinet for Health and Family Services, Office of Inspector General. A hospital utilizes acute care beds in providing medical services, including physician services and continuous nursing services for the diagnosis and treatment of patients who have a variety of medical conditions, both surgical and non-surgical.

A "special purpose acute care bed" includes, but is not limited to, an Intensive Care Unit bed, Cardiac Care Unit bed, Neonatal Level II ~~or~~, Level III, or Level IV bed and Obstetrics bed.

Review Criteria

An application to add additional acute care beds to an existing licensed hospital shall be consistent with this Plan if the following criteria are met:

1. The hospital can document that transfer or conversion of special purpose acute care beds to acute care beds is not feasible because occupancy in the special purpose acute care beds is greater than sixty-five (65) percent or if the occupancy is less than sixty-five (65) percent, the transfer of such beds would be insufficient to meet the hospital's total additional acute care bed need;

2. The hospital can document that:
   a. ~~The hospital can document that its~~ Its acute care occupancy rate has been higher than the target occupancy rate set forth in Table 1 below according to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report;* or,

Table 1
Facility Target Acute Care Bed Occupancy Rates

Number of Licensed beds per Facility	Facility Target Acute Care Bed Occupancy Percentage
1-50	60%
51 – 100	65%
101 – 200	70%
201 and above	75%

   b. ~~The hospital can document that its~~ Its utilization of acute care beds has reached functional capacity for the prior twelve (12) months. In calculating functional capacity, consideration shall be given to the percentage of licensed acute care beds, psychiatric beds and/or chemical dependency beds currently operational as well as other factors affecting the utilization at the hospital including, but not limited to, the mix of private and semi-private rooms, patient matching limitations

such as gender or the needs for isolation beds required to address emergency patient needs, and limits created by special purpose acute units; and

3. The maximum number of acute care beds that may be approved will be based on volume projected five (5) years from the date on which the hospital filed its application for additional acute care beds. Approval will be based on the higher of:

   a. The applicant's reasonable forecast of future utilization; or

   b. A regression analysis projection of patient day trends over a five (5) year timeframe.

C. Comprehensive Physical Rehabilitation Hospital Beds

Definition

For purposes of this Plan there shall be one category of rehabilitation beds called "comprehensive physical rehabilitation beds" which may be located in free-standing facilities or as units in acute care hospitals that provide therapy and training for rehabilitation. Such facilities offer a range of services that may include occupational therapy, physical therapy, and speech therapy to aid in the restoration of an individual to normal or near normal function after a disabling disease or injury.

Review Criteria

An application for comprehensive physical rehabilitation beds shall be consistent with this Plan if the following criteria are met:

1. An applicant that does not have existing licensed or certificate of need approved comprehensive physical rehabilitation beds and is proposing to establish such beds, shall demonstrate that the overall occupancy for comprehensive physical rehabilitation beds in the ADD exceeds seventy-five (75) percent as computed from the most recent published edition of the *Kentucky Annual Hospital Utilization and Services Report*.

2. Applicants proposing to expand the number of existing licensed comprehensive physical rehabilitation beds shall demonstrate that the occupancy of the existing comprehensive physical rehabilitation beds in the applicant's facility exceeds seventy-five (75) percent as computed from the most recent published edition of the *Kentucky Annual Hospital Utilization and Services Report*.

3. If criterion (1) or (2) is met, the maximum number of beds that may be approved in the ADD shall be computed by the following formula:

$$N = [((PD \div P) \times PP) \div (365 \times 0.75)] - (LB + AB)$$

Where:

N	=	Need for Comprehensive Physical Rehabilitation Beds in the ADD.
PD	=	The number of inpatient days in comprehensive physical rehabilitation beds ~~statewide~~ in the ADD as reported in the most recently published data.
P	=	Estimated population in the Commonwealth for the period used to derive patient days.
PP	=	Projected ~~2009~~ plan year population for the ADD.
0.75	=	The desired average annual occupancy rate for comprehensive physical rehabilitation beds in the ADD.
LB	=	Existing licensed comprehensive physical rehabilitation beds in the ADD.
AB	=	The number of comprehensive physical rehabilitation beds in the ADD for which a certificate of need has been granted.

4. The Cabinet may approve more rehabilitation beds than indicated by the need formula to allow for the presence of hospitals that provide a higher intensity of rehabilitation services than provided by most rehabilitation hospitals due to the in-migration of out-of-state patients or a high percentage of patient referrals for specialized services from other ADDs.

5. Notwithstanding criteria 1, 2 and 3, an applicant proposing to establish a comprehensive physical rehabilitation unit, within an existing acute care hospital with an existing licensed acute care bed inventory of at least one-hundred (100) beds, shall be consistent with the Plan if the following criteria are met:

   a. There are no other licensed or certificate of need authorized comprehensive physical rehabilitation beds in the proposed ADD; or

   b. There are no other licensed or certificate of need authorized comprehensive physical rehabilitation beds within forty-five (45) highway miles of the proposed site.

6. The maximum number of comprehensive physical rehabilitation beds that may be approved pursuant to criteria 5 will be based on volume projected five (5) years from the date on which the hospital filed its application for such beds. Approval will be based on the higher of:

   a. The applicant's reasonable forecast of future utilization; or

   b. A regression analysis of patient day trends over a five (5) year timeframe.

7. The minimum size for a new freestanding rehabilitation hospital shall be forty (40) beds and the minimum size for a new rehabilitation unit in an acute care hospital shall be ten (10) beds.

D. Special Care Neonatal Beds

Definition

"Special Care Neonatal beds" are licensed acute care beds located in hospital neonatal units that provide care and treatment of newborn infants through the age of twenty-eight (28) days, and longer if necessary.

Review Criteria

An application for Level II special care neonatal beds shall be consistent with this Plan if the following criteria are met:

1. Approval of the application does not cause the number of Level II beds to exceed the following calculation:

Maximum number of Level II beds in the ADD= (Total annual ADD births for the plan year ÷ 1000) • 4

2. The number of Level II beds in a facility shall be eight (8) per unit except in those cases where population distribution and access to Level II services justify a smaller unit. In no case shall a unit be smaller than four (4) beds;

~~3. The Cabinet determines that more Level II beds than indicated by the above calculation are justified in order to allow for the presence in the ADD of hospitals that provide a higher intensity of neonatal care than that provided by most hospitals due to a high percentage of neonatal patient referrals for complications that cannot be handled at the primary care level;~~

~~4~~3. No new Level II program shall be approved in an ADD unless the overall utilization of existing providers of Level II services in the ADD is at least seventy (70) percent as computed from the most recently published inventory and utilization data;

~~5~~4. No additional beds will be approved for an existing unit unless the utilization in this unit is at least seventy (70) percent as computed from the most recently published inventory and utilization data;

~~6~~5**.** The application documents consistency with the most recent published edition of the American Academy of Pediatrics and the American College of Obstetrics and Gynecology *Guidelines for Perinatal Care* and where superseded by the more recent official policy, the Policy Statement on Levels of Neonatal Care published by the American Academy of Pediatrics included as Attachment A; and

~~7~~6. In addition to the above criteria, an application for Level II special care neonatal care beds must document their ability to provide:

a. All services required of a Level I basic care neonatal bed.

b. Care only for stable or moderately ill newborn infants who are born at ≥ 32 weeks gestation or who weigh ≥ 1500 grams at birth with problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty-level services on an urgent basis.

c. Ventilation limited to an interim basis until the infant's condition either soon improves or the infant can be transferred to a higher-level facility. Delivery of continuous positive airway pressure should be readily available by experienced personnel, and mechanical ventilation can be provided for a brief duration (less than 24 hours).

d. Policies and procedures to ensure that care is provided by obstetricians and neonatologists who are continuously available (within 30 minutes) to provide ongoing care as well as to address emergencies.

e. Policies and procedures to ensure the appropriate equipment (eg, portable x-ray equipment, blood gas analyzer) are continuously available.

f. Policies and procedures to ensure personnel including specialized nurses, respiratory therapists, radiology technicians, and laboratory technicians shall be staffing the unit at all times.

g. Policies and procedures, including transfer agreements, to ensure referral to a higher level of care occurs for all infants born at < 32 weeks gestation or who weigh < 1,500 grams at birth or when needed for pediatric surgical or medical subspecialty intervention.

7. Not–withstanding the above criteria, if the most recently published inventory and utilization data indicates that the occupancy of existing special care Level II neonatal beds was seventy (70) percent or greater, an application to designate up to four (4) additional acute care beds as special care Level II neonatal beds shall be consistent with this plan.

An application for Level III special care neonatal beds shall be consistent with this Plan if:

1. Approval of the application does not cause the number of Level III beds in the Commonwealth to exceed the following calculation:

(Total annual state births for the plan year ÷ 1000) ● 1 = Maximum number of Level III beds in the state

~~2. The Cabinet determines that more Level III beds than indicated by the above calculation are justified in order to allow for the presence of hospitals that provide a higher intensity of neonatal care than that provided by most hospitals due to a high percentage of neonatal patient referrals for specialized services such as open-heart surgery, transplants, etc.;~~

~~3. No new Level III program shall be approved in the ADD unless the overall utilization of existing providers of Level III services in the ADD is at least seventy-five (75) percent as computed from the most recently published inventory and utilization data;~~

~~4. No additional beds shall be approved for an existing unit unless the utilization of this unit is at least seventy-five (75) percent as computed from the most recently published inventory and utilization data; and~~

~~5~~2. The application documents consistency with the most recent published edition of the American Academy of Pediatrics and the American College of Obstetrics and Gynecology *Guidelines for Perinatal Care* and where superseded by the more recent official policy, the Policy Statement on Levels of Neonatal Care published by the American Academy of Pediatrics included as Attachment A.

3. In addition to the above criteria, an application for Level III special care neonatal care beds must document their ability to provide:

a. All services required of a Level II special care neonatal care bed.

b. Personnel (neonatologists, neonatal nurses, and respiratory therapists) that are continuously available.

c. Equipment to provide life support for as long as needed that is continuously available.

d. Advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition and pharmacy support with pediatric expertise.

e. Ongoing assisted ventilation for periods longer than 24 hours, which may include conventional ventilation, high-frequency ventilation, and inhaled nitric oxide.

f. Maternal-Fetal Medicine Specialists and a broad range of pediatric medical subspecialists and pediatric surgical specialists that are readily accessible on site or by prearranged consultative agreements using telemedicine or telephonic consultation with. If provided by prearranged consultative agreements, explain the details of the prearrangement.

g. Readily available pediatric ophthalmology services in the level III facility and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity.

h. The policies and procedures in place to ensure that all complex surgical procedures performed in newborn infants are performed by pediatric surgical specialists (including anesthesiologists with pediatric expertise). The capability to perform major surgery may be on site if pediatric surgical and anesthesia specialists are available, or by arrangement with a closely related institution,

ideally in close geographic proximity. If capability is at a related institution, explain in detail arrangements that ensure the availability of transport services to quickly and safely transfer infants requiring this subspecialty intervention.

i. The capability to perform advanced imaging with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging, and echocardiography.

j. Documentation of the facility's participation in the Vermont-Oxford Network (VON), including the Kentucky State VON Report, to ensure the capability to collect data and assess outcomes within their facility and to compare with other levels; and, agree to submit a data report from the Vermont Oxford Network on outcomes of the facility's NICU to the Office of Health Policy annually.

k. Policies and procedures, including transfer agreements, to ensure referral to a higher level of care will occur for all infants requiring subspecialty intervention or surgical repair of complex conditions (eg, congenital cardiac malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation (ECMO). The Level III facility should ensure the availability of transport services to quickly and safely transfer infants requiring these subspecialty interventions to higher level facilities or children's hospitals.

4. Notwithstanding the above criteria, if the most recently published inventory and utilization data indicates that the occupancy of existing special care Level III neonatal beds was seventy (70) percent or greater, an application to designate up to two (2) additional Level II neonatal beds as special care Level III neonatal beds shall be consistent with this plan.

5. Notwithstanding the above criteria, applications proposing to convert up to fifty percent (50%) of existing Level II special neonatal beds, as published in the November 2012 Certificate of Need Inventory of Health Facilities and Services, to Level III special neonatal beds shall be consistent with the State Health Plan if the hospital is recognized as a "high intensity level II neonatal center" pursuant to 907 KAR 10:825.

An application for Level IV special care neonatal beds shall be consistent with this Plan if:

1. The application requests to convert a specified number of existing Level III neonatal beds to Level IV neonatal beds.

2. An application for Level IV special care neonatal care beds documents their ability to provide all services required of a Level III special care neonatal care bed.

3. The application for Level IV special care neonatal care beds documents their ability to provide pediatric medical subspecialists and pediatric surgical services within the institution, including anesthesiologists with pediatric expertise, as well as pediatric surgical subspecialists. These pediatric surgical subspecialist services, at a minimum, must include the ability to provide surgical repair of complex conditions e.g.,

congenital cardiac malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation (ECMO).

4. The application for Level IV special care neonatal care beds documents policies and procedures to facilitate transport systems and provide outreach education in their catchment area.

5. The application for Level IV special care neonatal care beds documents capability to collect data on long-term outcomes to evaluate both the effectiveness of delivery of perinatal health services and the safety and efficacy of new therapies.

E. Open Heart Surgery Program

Definition

Open heart surgery is any surgical procedure involving the heart, performed to correct acquired or congenital defects, to replace diseased valves, to open or bypass blocked vessels, or to graft a prosthesis or a transplant in place. In open-heart procedures, the heart chambers are open and fully visible and blood is detoured around the surgical field by a heart-lung bypass machine unless the procedure involved is a minimally invasive coronary artery bypass graft, in which case a heart-lung machine might not be used, but must still be available in the operating room on a stand-by basis.

A "case" is defined as the entire episode of treatment in the operating room regardless of the number of procedures performed.

Review Criteria

An application for an open heart surgery program shall be consistent with this Plan if the following criteria are met:

1. For adult open heart surgery, there is not an existing or approved open heart surgery program in the ADD or the following criteria are met:

    a. According to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*, every open heart surgery program in the ADD performed at least four hundred (400) adult open-heart surgeries;

    b. According to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*, every open heart surgery program within a fifty (50) mile radius of the proposed site performed at least four hundred (400) adult open-heart surgeries;

    c. Every open heart surgery program in the ADD that is not listed in the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report* performed at least three hundred (300) adult open-heart surgeries in the past twelve (12) months;

    d. Every open-heart surgery program that is within a fifty (50) mile radius of the proposed site and is not listed in the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report* performed at least three hundred (300) adult open heart surgeries in the past twelve (12) months;

    e. The applicant shall document that at least four hundred (400) adult open-heart procedures will be performed during the third year of operation. These projections must consider historical number of diagnostic cardiac catheterization procedures performed at the applicant hospital, the Kentucky statewide ratio of open heart surgeries to diagnostic catheterization procedures as calculated in the

latest published inventory and utilization data, and documentation of the number of diagnostic catheterization patients referred for open heart surgery from the applicant hospital during the most recent twelve (12) month period;

f. The applicant shall document that the approval of the proposed program will not cause any existing program in the ADD or any other open heart surgery program within a fifty (50) mile radius of the proposed site to fall below four hundred (400) cases annually when considering historical trends in utilization, referral patterns for such services to existing providers, and commonality of medical staffs;

g. The applicant shall demonstrate that the projected number of therapeutic cardiac catheterization procedures will reach at least three hundred-fifty (350) by the third year of operation of the open heart surgery program. These projections must consider historical diagnostic cardiac catheterization procedures at the applicant hospital, the Kentucky statewide ratio of therapeutic catheterizations to diagnostic catheterizations patients and documentation of the historical number of diagnostic cardiac catheterization patients referred from the applicant hospital for therapeutic cardiac catheterization during the most recent twelve (12) month period. Applicants shall also document compliance with the requirements for therapeutic catheterization under the Cardiac Catheterization Services section, criterion eleven, of these Review Standards;

h. The applicant shall document that the most recently published *Guidelines for Coronary Artery Bypass Graft Surgery* adopted by the American College of Cardiology and the American Heart Association will be followed; and

i. The applicant must identify the surgeon who will be the primary attending surgeon in the open heart service. Further, the applicant must also provide information regarding this individual's background and experience concerning open heart surgery, and this individual's availability to care for open heart patients in the event of emergencies.

2. For pediatric open heart surgery:

a. Only pediatric teaching facilities shall be approved for pediatric open heart surgery;

b. According to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*, every existing pediatric program in the state shall be performing, and shall be projected to continue to perform at least one hundred-fifty (150) pediatric open-heart surgeries per year; and

c. The applicant shall document that at least one hundred (100) pediatric open-heart procedures will be performed during the third year of operation.

F. Organ Transplant Program

Definition

Transplant procedures involve the transfer of an organ or tissue from one person to another, or from one body part to another, to replace a diseased structure, to restore function, or to change appearance. Skin and kidneys are among the more commonly transplanted structures; others include hearts, livers, lungs, pancreas, cartilage, bone marrow, corneal tissue, portions of blood vessels and tendons.

Review Criteria

An application for an organ transplant program shall be consistent with this Plan if the following criteria are met:

1. The applicant documents that the number of transplants being performed by comparable transplant programs in the Commonwealth are sufficient for consistency with nationally accepted volume and quality standards for each type of transplant program; the record of medical outcomes by those programs; and the impact on need for additional transplant programs in Kentucky resulting from the existence of transplant programs in nearby cities of bordering states that are customarily and significantly used by Kentucky residents;

2. The applicant documents that it has the ability to meet nationally accepted volume and quality standards, as well as those factors that impact patient care and overall cost, quality and outcomes of service delivery, including demographic and epidemiological factors;

3. For pediatric programs, the pediatric program shall be provided in a pediatric teaching facility which has the availability of physician specialty support and specialized ancillary support services; and

4. The applicant demonstrates that organ allocation for patients awaiting transplantation shall be performed in accordance with federally mandated guidelines.

II. Mental Health Care

A. Psychiatric Hospital Beds

Definition

"Psychiatric beds" are those licensed beds which are located in psychiatric hospitals or as units in an acute care hospital or a critical access hospital and are used for treatment of inpatients that require psychiatric or mental health care, including medical care and treatment of mental, emotional, and behavioral disorders.

Review Criteria

An application for psychiatric beds shall be consistent with this Plan if the following criteria are met:

1. Licensed and approved adult and geriatric psychiatric beds in an ADD shall not exceed 0.2 beds per 1,000 geographic adult and geriatric population for the plan year. Licensed and approved children or adolescent psychiatric beds in an ADD shall not exceed 0.2 beds per 1,000 geographic child and adolescent population for the plan year. Statewide psychiatric care facilities operated or contracted by the Commonwealth shall not be counted in the existing bed count;

2. Any existing acute care facility or psychiatric hospital proposing the addition of adult psychiatric beds shall exceed the target occupancy rates shown in Table 1 below for its licensed and allocated adult psychiatric care beds for the most recent twelve (12) month period reported in the most recently published edition of the *Kentucky Annual Hospital Utilization and Services Report* unless all the proposed additional psychiatric care beds are being converted from licensed acute care beds;

Table 1

Facility Target Psychiatric Bed Occupancy Rates

# Beds in Facility	Target Occupancy
1-50	60%
51-100	65%
101-200	70%
201 and above	75%

3. No additional adult psychiatric beds shall be approved for purposes of establishing a new facility or a new unit unless ~~overall~~ occupancy for ~~all~~ each facility with licensed and allocated adult psychiatric beds in the ADD exceeds the target occupancy rates shown in

Table 1 according to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*;

4. Any existing acute care facility or psychiatric hospital proposing the addition of child or adolescent psychiatric beds shall exceed the target occupancy rates shown in Table 1 above for its licensed and allocated child or adolescent psychiatric care beds for the most recent twelve (12) month period reported in the most recently published edition of the *Kentucky Annual Hospital Utilization and Services Report* unless all the proposed additional psychiatric care beds are being converted from licensed acute care beds;

5. No additional child or adolescent psychiatric beds shall be approved for purposes of establishing a new facility or a new unit unless occupancy for each facility with licensed and allocated child or adolescent psychiatric beds in the ADD exceeds the target occupancy rates shown in Table 1 according to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*;

~~4~~6. If the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report* indicates that the occupancy for existing psychiatric beds for an applicant's facility was seventy (70) percent or greater, an application to convert acute care beds to psychiatric beds shall be consistent with this Plan if the application meets either of the following conditions:

a. The applicant meets the review criteria in Sections 1, 2, and 3 above, or 1,4, and 5 above, or

b. The applicant has existing licensed acute care beds and psychiatric beds, and:

i. All of the proposed psychiatric beds are being converted from licensed acute care beds;

ii. The occupancy of acute care beds is less than seventy (70) percent in the latest published utilization and inventory data; and

iii. The additional psychiatric beds will be converted and implemented on-site at the applicant's existing licensed acute care facility.

~~5~~7. If the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report* indicates that the occupancy for existing psychiatric beds for an applicant's facility was seventy (70) percent or greater, an application to convert chemical dependency beds to psychiatric beds shall be consistent with this plan if the application meets either of the following conditions:

a. The applicant meets the review criteria in Sections 1, 2, and 3 above, or 1, 4 and 5 above, or

b. The applicant has existing licensed chemical dependency beds and psychiatric beds, and:

i. All of the proposed psychiatric beds are being converted from licensed chemical dependency beds;

ii. The conversion will not impede access to appropriate care for patients needing treatment for abuse or addiction to chemical substances such as alcohol or drugs; and

iii. The additional psychiatric beds will be converted and implemented on site at the applicant's existing licensed acute care or chemical dependency facility.

~~6~~8. Notwithstanding the above criteria, an application to add psychiatric beds to an existing licensed psychiatric unit or psychiatric hospital shall be consistent with this Plan if the applicant demonstrates that its utilization of its existing psychiatric beds has reached functional capacity for the prior twelve (12) month period. In calculating functional capacity consideration shall be given to the following:

a. The percentage of licensed acute care beds, psychiatric beds and/or chemical dependency beds currently operational;

b. The type and level of psychiatric care being provided at the applicant's facility;

c. The historical performance as it relates to the utilization of psychiatric beds; and

d. The availability of other providers of psychiatric services in the ADD.

~~7~~9. The maximum number of psychiatric care beds that may be approved shall be based on volume projected five (5) years from the filing of the application. Approval will be based on the higher of:

a. The applicant's credible forecast of future utilization; or

b. A regression analysis projection of patient day trends over a five (5) year timeframe.

Psychiatric Services for Children and Adolescents

In addition to the above criteria, an application for child or adolescent psychiatric beds shall be consistent with this Plan if the following criteria are met:

1. The applicant shall provide clear descriptions of which evidence-based practices will be utilized and how they will meet the clinical needs of the proposed population to be served.

2. New hospital psychiatric beds for children or adolescents shall focus on short-term (under thirty days) crisis stabilization. Small, specialized programs are preferred over larger programs;

~~2~~3. A facility proposing to provide inpatient psychiatric care for children twelve (12) years of age and younger shall have on staff a board-eligible or board-certified child psychiatrist who maintains responsibility for admissions and treatment. For the purposes of this section, a board-eligible child psychiatrist is a doctor of psychiatry who has been board-certified in general psychiatry by the American Board of Psychiatry and Neurology and has completed a two (2) year fellowship in child psychiatry;

~~3~~4. An application for new psychiatric beds for children or adolescents shall include all of the following:

a. The specific number of beds proposed for each age group;

b. An inventory of current services in the ADD;

c. Clear admission and discharge criteria consistent with a short-stay program and least restrictive treatment;

d. Linkage agreements with other child and adolescent serving agencies in the proposed service areas, including all regional interagency councils (RIACs), community mental health centers, the Department for Community Based Services, and major referring school systems. These agreements should demonstrate a commitment by these agencies and the hospital to joint treatment and discharge planning as appropriate; and

e. Documentation of linkage agreements for the provision for case management services when necessary after discharge. (Case managers need not be on the hospital's staff, but should be closely involved in cases from treatment planning onward).

f. Documentation of the policies and procedures to ensure a case manager will be identified and an appointment scheduled as part of the discharge planning process; and in the case of a child the case manager shall be involved in the discharge planning process.

Geriatric Psychiatric Services

An application to establish non-Medicaid inpatient geriatric psychiatric programs in an existing licensed acute care facility located in a county that has no existing inpatient geriatric psychiatric program shall be considered consistent with this Plan if the following conditions are met:

1. The occupancy of acute care beds in the applicant's facility is less than seventy (70) percent according to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*;

2. All of the proposed psychiatric beds are being converted from licensed acute care beds;

3. All of the psychiatric beds will be converted and implemented on-site at the applicant's existing licensed acute care facility;

4. All of the converted psychiatric beds shall be dedicated exclusively to the treatment of geriatric patients, aged sixty-five (65) or older;

5. The hospital shall establish distinct admission and discharge criteria for admitting only those patients who have both mental and physical conditions who would be excluded from treatment in a regular adult psychiatric unit;

6. The staff of the unit shall include a multidisciplinary team of specialists involving psychiatry and internal medicine with specialization in the treatment of geriatrics and nursing personnel specially trained in psychiatric and medical geriatric patient care; and

7. The applicant agrees in writing not to seek Medicaid certification for the converted beds.

B. Psychiatric Residential Treatment Facility

Definition

"Psychiatric residential treatment facility" (PRTF) means either a licensed:

Level I community-based, and home-like facility with a maximum of nine (9) beds which provides inpatient psychiatric residential treatment to residents age six (6) to twenty-one (21) years who have an emotional disability or severe emotional disability as defined in KRS 200.503, with an age range of no greater than five (5) years at the time of admission in a living unit; or

Level II home-like facility that provides twenty-four (24) hour inpatient psychiatric residential treatment and rehabilitation to persons who:

1. Are ages four (4) to twenty-one (21) years, with an age range of no greater than five (5) years at the time of admission to the facility;

2. Have a severe emotional disability as defined by KRS 200.503 in addition to severe and persistent aggressive behaviors, intellectual disability, sexually acting out behaviors, or development disability; and

3. Do not meet the medically necessity criteria for an acute care hospital or a psychiatric hospital and whose treatment needs cannot be met in an ambulatory care setting, Level I psychiatric residential treatment facility, or other less restrictive environment.

"Specialty Program" means programs offered by a Level II Psychiatric residential treatment facility to treat a person who has a severe emotional disability as defined by KRS 200.503 in addition to severe and persistent aggressive behaviors, intellectual disability, sexually acting out behaviors, or development disability.

Review Criteria

Level I PRTF

An application to establish a PRTF or expand an existing PRTF shall be consistent with this Plan if the following criteria are met:

1. Approval of the application does not cause the total number of Level I PRTF beds to exceed three hundred and fifteen (315) beds statewide.

2. The applicant shall document the need for additional Level I PRTF services and their ability to provide those services by demonstrating the following:

    a. An analysis of the number and characteristics of persons ages six (6) to twenty-one (21) in the proposed service area who require this level of care;

b. The defined geographic service area that the proposed facility will serve;

c. The anticipated average length of stay, average daily census, and occupancy rate;

d. The projected payor mix of the patients;

e. The anticipated referral sources including the projected number of DCBS children in state custody who would be admitted; and

f. Clear admission and discharge criteria with specific descriptions of any special defining characteristics of the population that is proposed to be served, including age, sex, developmental status, legal status, and diagnostic characteristics.

3. The applicant shall include an inventory of all types of treatment oriented residential programs including other Level I PRTFs, that serve children ages six (6) to twenty-one (21) in the proposed serviced area and how the proposed facility or additional beds fit into the array of current services.

4. The applicant shall clearly describe the treatment planning and the discharge planning process, including how the family, or legal guardian would be included in the treatment and discharge process. For children in state custody, describe how the Department for Community Based Services (DCBS) staff will be included in the treatment and discharge planning process. For children who attain age 21 that need to be transitioned to the adult system, describe the transition and discharge planning process to the adult system.

5. The applicant shall provide clear descriptions of which evidence based clinical practices will be utilized and how they will meet the clinical needs of the proposed population to be served.

6. Applicants shall describe the types and qualification of personnel required to provide services, including certification specific to the programs being proposed, and a detailed description of the availability of qualified staff.

7. The applicant shall provide a description of the proposed facility, physical layout, description of individual unit sizes and proximity to other programs and facilities that might be housed on the same campus or in close proximity, either operated by the same applicant or other organizations or demonstrating clearly defined relationships.

8. The applicant shall provide a description of how the proposed Level I PRTF's individual living units and program spaces will provide a safe environment and be community based and home-like in physical appearance and structure, but also in terms of family visitation policies and contact with significant adults in their lives.

9. Applications to establish a Level I PRTF shall include formal written agreements of cooperation that identify the nature and extent of the proposed working relationship

between the facility and the following agencies, organizations, or entities located in the primary service area of the proposed facility:

a. Regional interagency council for services to children with an emotional disability created under KRS 200.509;

b. Community mental health-mental retardation board established under KRS 210.380;

c. The Department for Community Based Services;

d. Local school districts in the county where the PRTF is located;

e. At least one psychiatric hospital; and

f. Linkages with other child and adolescent serving agencies in the proposed service area.

10. Priority shall be given to applicants that demonstrate the capacity to provide or have access to a full array of other community-based services, and applicants that demonstrate the adoption of system of care principles and the wraparound process which include family driven and youth guided programming and treatment.

Level II PRTF

An application to establish a Level II PRTF or expand an existing Level II PRTF shall be consistent with this Plan if the following criteria are met:

1. Approval of the application does not cause the total number of Level II PRTF beds to exceed one hundred forty-five (145) beds statewide.

2. The application to establish a Level II PRTF does not exceed fifty (50) Level II PRTF beds.

3. Approval of the application to expand an existing Level II PRTF does not cause the existing Level II PRTF to exceed fifty (50) Level II PRTF beds in a facility.

4. The applicant shall:

a. Fully describe the specific Specialty Program to be provided and the target population to be served in the proposed Level II PRTF, including each specific age and gender;

b. Specify the defined geographic service area that the proposed facility will serve;

c. Indicate the specific number of beds proposed for each age group and specific Specialty Program, based on diagnoses, that the Level II PRTF is proposing to offer;

d. Document the anticipated average length of stay, average daily census, and occupancy for each age group and Specialty Program;

e. Document the projected payor mix of the patients, including Medicaid and DCBS children in state custody;

f. Document the need for Level II PRFT beds requested, based on historical patient data from patients that have been sent out of state or other substantiated data to demonstrate the need for Level II PRTF services and the number of beds and type of specialty program services proposed; and

g. Clear admission and discharge criteria for each Specialty Program listed above, including age, sex, developmental status, legal status, and diagnostic characteristics.

5. The applicant shall include an inventory of Level II PRTFs that serve children ages four (4) to twenty-one (21) in the proposed service area and how the proposed facility or additional beds will fit into the array of current services.

6. The number of beds requested for each specialized program shall be calculated using an annual average occupancy rate of 75 percent.

7. The applicant shall document that the facility or program shall not refuse to admit a patient who meets the medical necessity criteria and facility criteria for Level II PRTF services.

8. The applicant shall clearly describe the treatment planning and the discharge planning process, including how the family, or legal guardian would be included in the treatment and discharge process. For children in state custody, describe how the Department for Community Based Services (DCBS) staff will be included in the treatment and discharge planning process. For children who attain age 21 that need to be transitioned to the adult system, describe the transition and discharge planning process to the adult system.

9. The applicant shall provide clear descriptions of which evidence based clinical practices will be utilized and how they will meet the clinical needs of the proposed specialty population to be served and how staff will be trained, supervised, and how accuracy to the evidence based practice will be monitored.

10. Applicants shall describe the types and qualification of personnel required to provide services, including certification specific to the programs being proposed, and a detailed description of the availability of qualified staff and how the facility will immediately

obtain additional staff as may be needed to ensure the safety of patients.

11. The applicant shall provide a description of the proposed facility, physical layout, description of individual unit sizes and proximity to other programs and facilities that might be housed on the same campus or in close proximity, either operated by the same applicant or other organizations or demonstrating clearly defined relationships.

12. The applicant shall provide a description of how the proposed Level II PRTF's individual living units and program spaces will provide a safe environment and be home-like in physical appearance and structure, but also in terms of family visitation policies and contact with significant adults in their lives.

13. Applications to establish a Level II PRTF shall include formal written agreements of cooperation that identify the nature and extent of the proposed working relationship between the facility and the following agencies, organizations, or entities located in the primary service area of the proposed facility:

    a. Regional interagency council for services to children with an emotional disability created under KRS 200.509;

    b. Community mental health-mental retardation board established under KRS 210.380;

    c. The Department for Community Based Services;

    d. Local school districts in the county where the PRTF is located;

    e. At least one psychiatric hospital, if the applicant is not a psychiatric hospital or an acute care hospital that provides inpatient psychiatric services for adolescents or children; and

    f. Linkages with other child and adolescent serving agencies in the proposed service area.

14. In approving Level II PRTF applications, consideration shall be given to the geographic location and specialty program offered by the proposed facility to ensure that Level II ~~PFTF~~ PRTF specialty programs are provided in different geographic areas of the State.

15. Priority shall be given to applicants that demonstrate the capacity to provide or have access to a full array of other community-based services, and applicants that demonstrate the adoption of system of care principles and the wraparound process which include family driven and youth guided programming and treatment.

III. Long-Term Care

A. Nursing Facility Beds

Definition

"Nursing Facility Bed" includes long-term care beds licensed as Alzheimer beds, intermediate care beds, skilled nursing beds, nursing facility beds, and nursing home beds; and

Nursing Facility Beds do not include personal care beds, nursing home beds established under the continuing care retirement community (CCRC) provisions of this Plan, or long-term care beds located in state or federally-operated facilities.

Need Assessment for Nursing Facility Beds

The need for additional nursing facility beds in each county shall be calculated as follows:

A = B - C

Where:

A = The net county NF bed need.

B = The number of patients from the applicant's proposed county of location who found NF bed placement in a noncontiguous county as reported in the most recently published *Kentucky Annual Long-Term Care Services Report*.

C = The average number of empty beds in the county of application and all counties contiguous to the county of application. The average number of empty beds for a county shall be calculated by multiplying the number of non-state owned and non-CCRC licensed NF beds times the occupancy percentage for the county as reported in the most recently published *Kentucky Annual Long-Term Care Services Report*.

Review Criteria

An application for nursing facility beds shall be consistent with this Plan if the following criteria are met:

1. The number of nursing facility beds being applied for is equal to or less than the net county NF bed need; and

2. Any approval shall give preference to conversion of personal care beds and acute care beds to nursing facility beds so long as the conversions are more cost effective than new construction.

3. Notwithstanding the above criteria, an application submitted by an existing facility that has met the emergency circumstances provision as outlined in 900 KAR 6:080 Section 2 and has received notice from the Office of Health Policy that an emergency exists, shall be consistent with this Plan only if the application is restricted to the limited purpose of alleviating the emergency.

B. Home Health Service

Definitions

"Energy Employees Occupational Illness Compensation Program (EEOICPA)" means the program passed by Congress to provide compensation to persons who have become ill as a result of work at atomic weapon facilities. Individuals enrolled in the program receive free in-home skilled nursing care and pay no deductible or co-payment amounts.

"Home Health Services" refers to a combination of health care and social services provided to individuals in their homes or in other community and homelike settings pursuant to 902 KAR 20:081.

"To establish a home health service" means to establish a parent home health agency or a subunit as defined by Medicare in a county where the applicant is not currently licensed to serve.

"To expand a home health service" means to add to the applicant's existing service area a county or counties which are contiguous to the applicant's existing service area provided that the expansion does not involve the establishment of a parent home health agency or subunit as defined by Medicare.

Summary of Need Criteria

The need for home health services is determined on a county-by-county basis by applying target rates estimating the number of individuals per 1,000 population expected to require home health services. Age cohort target rates are calculated for the plan year and are based on the average number of unduplicated patients served statewide in each age cohort for the most recent two calendar years in the *Kentucky Annual Home Health Services Report*. Age cohort rates are applied to the plan year county population projections to determine expected need for home health services. The number of additional patient services needed in a county is then determined by subtracting the average number of unduplicated patients served in the county for the most recent two calendar years, as reported in the *Kentucky Annual Home Health Services Report*, from projected need. The number of unduplicated patients served under EEOICPA will not be considered when projecting need.

The inventory for patients expected to be served will be adjusted by the addition of two hundred-fifty (250) patients for each certificate of need approved to establish a new agency or subunit in a specific county, by one hundred twenty-five (125) patients for each application approved to expand a home health service to a specific county, and by fifty (50) patients for each application approved for a hospital to establish an agency to solely serve the county in which the hospital is located. The respective number of patients will be removed from the inventory for patients to be served when the latest edition of the *Kentucky Annual Home Health Services Report* indicates that the agency has served patients in the approved county. The inventory for patients expected to be served will not be adjusted to reflect certificate of need approvals which were restricted to the limited purpose of alleviating an emergency. The inventory for patients expected to be

served will not be adjusted to reflect certificate of need approvals for services provided under the EEOICPA program.

Review Criteria

1. An application to establish a home health service shall be consistent with this Plan if there is a projected need for at least two hundred-fifty (250) additional patients needing home health care services in the county for which the application is made as shown in the most recent edition of the *Kentucky Annual Home Health Services Report*.

2. An application to expand a home health service currently licensed in Kentucky shall be consistent with the Plan if there is a projected need for at least one hundred twenty-five (125) additional patients needing home health care services in the county for which the application is made as shown in the most recent edition of the *Kentucky Annual Home Health Services Report*.

3. Notwithstanding Criterion 1 and 2, an application submitted by an existing agency that has met the emergency circumstances provision as outlined in 900 KAR 6:080 Section 2 and has received notice from the Office of Health Policy that an emergency exists, shall be consistent with this Plan only if the application is restricted to the limited purpose of alleviating the emergency.

4. Notwithstanding Criterion 1, 2, and 3, an application submitted for the sole purpose of providing in-home nursing care to individuals eligible for benefits under the EEOICPA program is consistent with this plan.

C. Hospice Service

Definition

"Hospice Services" provide symptom relieving care and supportive services through an interdisciplinary approach that addresses the physical, spiritual, social, and economic needs of terminally ill patients and their families. Services include home care, inpatient care, bereavement services, counseling, and education. Emphasis is placed on symptom control and pain control for the terminally ill person, support for the patient before death, and support for the family before and after death.

Need Assessment for Hospice Services

The need for additional Hospice Services shall be calculated on a county-by-county basis as follows:

$$\text{HPR} = \frac{\text{(Year (n) Admissions * 0.50) + (Year (n-1) Admissions * 0.30) + (Year (n-2) Admissions * 0.20)}}{\text{(Year (n) Deaths * 0.50) + (Year (n-1) Deaths * 0.30) + (Year (n-2) Deaths * 0.20)}}$$

Where:

HPR	=	Hospice Penetration Rate
Year (n)	=	Year of the most recently published report
Year (n-1)	=	Year of the second most recently published report
Year (n-2)	=	Year of third most recently published report
Admissions	=	Unduplicated ~~Hospice~~ hospice admissions utilizing data published in the three (3) most recent editions of the *Kentucky Annual Hospice Services Report.*
Deaths	=	Deaths from all causes (excluding deaths resulting from suicide, homicide or unintentional injuries) as reported in the three (3) most recent editions of the Kentucky Department for Public Health, *Vital Statistics Report*

Review Criteria

An application to establish or expand hospice services shall be consistent with this Plan if:

1. a. The hospice penetration rate in the proposed county is less than eighty (80) percent of the median hospice penetration rate statewide; and the proposed county is located in an ADD where the mean hospice penetration rate of the counties within the ADD is less than eighty (80) percent of the median hospice penetration rate statewide;

b. Each approved hospice agency in the proposed county has been operational for at least thirty six (36) months; and

c. Only one (1) application may be approved in each county during any batching cycle.

2. Notwithstanding the above criterion, an application to establish or expand hospice services into an individual county shall be consistent with this plan if the applicant documents the existence of at least one of the following conditions:

a. Absence of services by a hospice certified for Medicaid and Medicare in the proposed county, and evidence that the applicant will provide Medicaid and Medicare-certified hospice services in the county; or

b. Absence of services by a hospice in the proposed county that serves patients regardless of the patient's ability to pay, and evidence that the applicant will provide services for patients regardless of ability to pay.

D. Residential Hospice Facility

Definition

A “Residential Hospice Facility” is licensed pursuant to 902 KAR 20:380 and provides residential care for terminally-ill patients that include skilled nursing care for the management of pain and acute and chronic symptoms.

Review Criteria

No application to establish a residential hospice facility shall be approved under this Plan.

E. Adult Day Health Care Program

Definition

"Adult Day Health" is the provision of outpatient health care services that meet the health care needs of patients in conformance with physician's orders and without which would cause the patient and patient's health to meet the criteria for nursing home level of care.

Review Criteria

An application for an Adult Day Health Care Program shall be consistent with this Plan if the following criteria are met:

1. The applicant documents that the following services will be provided:

    a. One (1) meal per day including special diets;

    b. Snacks as appropriate;

    c. Daily on-site nursing services and supervision provided by RN or LPN including administration of medications and treatments as ordered by a patient's physician;

    d. Regularly scheduled activities specific to patient's age and care plan;

    e. Routine services required to meet daily personal care and health care needs; and

    f. Equipment essential to the provision of Adult Day Health Care Services and incidental supplies necessary to provide Adult Day Health Care services;

2. The applicant documents the capacity of providing necessary transfer and referral services should a patient's needs become such that a different level of care would be more beneficial; and

3. The applicant demonstrates the ability to maintain appropriate medical records and follow accepted universal precaution practices.

F. Intermediate Care Facility for the Mentally Retarded & Developmentally Disabled

Definition

"Intermediate Care Facilities for the Mentally Retarded and Developmentally Disabled" ("ICF-MR/DD") provide services for all age groups on a twenty-four (24) hour basis, seven (7) days a week, in an establishment with permanent facilities including resident beds for persons whose mental or physical condition requires developmental nursing services along with a planned program of active treatment. The facility provides special programs as indicated by individual care plans to maximize the resident's mental, physical, and social development in accordance with the normalization principle.

Review Criteria

No application for a new ICF-MR/DD shall be consistent with this Plan unless it is limited to a transfer of ICF-MR/DD beds from an existing ICF-MR/DD facility to the proposed ICF-MR/DD facility. No application to increase the number of beds at an existing ICF-MR/DD facility shall be consistent with the Plan unless the increase in beds is accomplished by transferring beds from an existing ICF-MR/DD facility.

IV. Diagnostic and Therapeutic Equipment and Procedures

A. Cardiac Catheterization Service

Definition

"Cardiac Catheterization" is a diagnostic or therapeutic procedure in which a catheter is introduced into a large vein or artery, usually of an arm or a leg, and threaded through the circulatory system to the heart. A single procedure lasts from the time the catheter is inserted until the time that the catheter is completely withdrawn from the patient. To determine the number of cardiac catheterizations performed, each administrative claims record submitted pursuant to KRS 216.2920 – 2929 and 900 KAR 7:030 is examined to determine if it contains procedure codes indicating diagnostic catheterization or therapeutic catheterizations as defined below. Inpatient Hospital Discharge records are examined for ICD-9 Procedure codes as published in the most recent Professional Edition ICD-9-CM manual for Hospitals Volume 3, while Outpatient Services Records are examined for CPT Procedure codes as published in the most recent Professional Edition Current Procedural Terminology manual. As published in the *Annual Administrative Claims Data Report*, diagnostic includes a count of the number of administrative claims records where the record included a Diagnostic Code regardless of the presence of any additional Therapeutic code(s). Therapeutic includes a count of the number of administrative claims records where the record included a Therapeutic Code regardless of the presence of any additional Diagnostic code(s).

"Diagnostic" cardiac catheterization means providing diagnostic only cardiac catheterizations on an organized, regular basis, in a laboratory. The term includes, but is not limited to: the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic). ~~The term also includes cardiac permanent pacemaker/ICD device implantations in a hospital that does not provide therapeutic cardiac catheterization services.~~

"Therapeutic" cardiac catheterization means a classification of invasive procedures in which a slender tube is passed into a peripheral vein or artery, through the blood vessels, and into the heart to treat and resolve anatomical and/or physiological problems in the heart. These procedures are intended primarily for the treatment of cardiac disease. The term includes percutaneous coronary intervention (PCI), percutaneous transluminal coronary angioplasty (PCTA), atherectomy, and stent. The use of clot-dissolving infusion drugs approved by the FDA such as Streptokinase and TPA does not constitute the provision of therapeutic cardiac catheterization.

With regard to cardiac catheterization services the term "Laboratory" means each dedicated room within a fixed-site facility which is individually equipped and staffed for the purposes of performing cardiac catheterizations.

With regard to cardiac catheterization services, the "Planning Area" shall be comprised of the county of the proposed cardiac catheterization program and all contiguous counties.

Review Criteria

An application proposing to provide cardiac catheterization services shall be consistent with this Plan if the following criteria are met:

1. For applicants proposing fixed site diagnostic cardiac catheterization only:

    a. The applicant is licensed by the Kentucky Office of Inspector General, Division of Health Care Facilities as an acute care hospital pursuant to 902 KAR 20:016;

    b. According to the most recent edition of the *Kentucky Annual Administrative Claims Data Report*, each existing fixed-site diagnostic laboratory in the planning area shall have performed at least two hundred and fifty (250) adult diagnostic procedures in the last twelve (12) month reporting period. Each existing fixed-site comprehensive laboratory (diagnostic and therapeutic) shall have performed at least five hundred and fifty adult procedures (550) in the last twelve month reporting period;

    c. The total projected number of adult diagnostic catheterizations in the planning area shall exceed the total existing adult procedures by at least two hundred and fifty cases (250) procedures by the end of the third year of operation;

        i. The total projected number of adult procedures will be based on the adult diagnostic cardiac catheterization use rate for the Commonwealth of Kentucky for the most recent twelve (12) month period for which data are published in the *Administrative Claims Data Report* ~~available~~ applied to the projected planning area population three (3) years in the future from the date the application was filed; and

        ii. The number of diagnostic cardiac catheterization procedures performed by existing programs, according to the most recent edition of the *Kentucky Annual Administrative Claims Data Report* will be subtracted from the total projected diagnostic procedures for the planning area. If there are approved but not operational fixed-site laboratories or lab not included in the most recently published *Kentucky Annual Administrative Claims Data Report* , an additional two hundred and fifty (250) procedures will be subtracted from the total for each.

    d. The applicant has established a cardiology program as evidenced by the availability of at least two (2) board certified cardiologist with medical staff privileges at the applicant's hospital.

2. For applicants proposing to expand their existing diagnostic cardiac catheterization service to also provide primary (i.e. emergency) Percutaneous Coronary Intervention (PCI) services on a two (2) year trial basis:

a. The applicant shall be an existing acute care hospital;

b. The applicant must have performed, according to the most recent edition of the *Kentucky Annual Administrative Claims Data Report*, an average of at least three hundred (300) annual diagnostic cardiac catheterization procedures during the previous two (2) years. The number of diagnostic cardiac catheterization procedures provided out-of-state to residents of the hospital's primary service area shall also be included in determining the hospital's compliance with the required number of diagnostic cardiac catheterization procedures if:

(1) The hospital provides an affidavit that physicians with staff privileges at the hospital performed the diagnostic cardiac catheterization procedures on the Kentucky patients at an out-of-state hospital, and

(2) The hospital can produce data showing the number of out-of-state diagnostic cardiac catheterization procedures performed on Kentucky patients from the hospital's primary service area from a credible data source;

c. The applicant must demonstrate that the facility will perform at least thirty six (36) primary PCI procedures per year by the end of the second year of operation;

d. The applicant's primary PCI services will be available on a continuous twenty four (24) hour per day basis;

e. The applicant's staff involved in providing PCI, including interventional cardiologists, nurses and technicians must have a current advanced cardiac life support (ACLS) certification;

f. The applicant's catheterization laboratory must be optimally equipped;

g. Case selection must be rigorous and limited to patients with acute myocardial infarction (defined as both ongoing chest pain and ST-segment elevation or new left bundle branch block on the electrocardiogram);

h. The applicant must establish an ongoing program of outcomes analysis and formalized periodic case review;

i. The applicant shall have an agreement with an ACLS-capable ambulance service stating that the service will respond to a call from that facility in no greater than thirty (30) minutes and meet all American College of Cardiology (ACC) requirements for transporting heart patients and provide evidence that EMS or air transport has the capability to transport a patient with a balloon pump;

j. There must be an image transfer system in place between the applicant's hospital and the backup cardiac surgical facility with capabilities for immediate consultation between the applicant's cardiologist and the surgical facility's cardiothoracic surgeon or interventional cardiologist;

k. The applicant's program director must have performed at least five hundred (500) career PCI procedures over a life time and be board certified by the American Board of Internal Medicine in interventional cardiology;

l. The applicant must participate in the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) quality measurement program; and

m. The application shall contain a current, signed collaboration agreement with a tertiary hospital that has an active comprehensive cardiac surgical program (including open heart surgery) within the facility. This agreement shall commit the tertiary hospital to the following actions:

i. Provide continuous twenty four (24) hours per day availability of consultation to the physician and nursing staff of the applicant's participating hospital in the care of patients that are candidates for and/or have received primary angioplasty;

ii. Develop and participate in a joint performance improvement program, with the participant hospital, which includes all disciplines (i.e., physicians, nurses and technicians from the staffs of both the applicant's participating hospital and the collaborating tertiary hospital) providing patient care and focuses on patient outcomes;

iii. Develop and participate in joint in-service education programs for all staff (including physicians, nurses and technicians) at the collaborating hospital. The in-service education programs will be based upon needs identified in the processes of staff evaluation and the performance improvement program; and

iv. Collaborate with the applicant's participating hospital to undergo peer review of the first one hundred and fifty (150) therapeutic cardiac catheterization procedures in collaboration with the tertiary hospital through the Joint Performance Improvement Committee. A peer review shall be conducted for all patients who were either transferred to the tertiary hospital or experienced an adverse outcome as defined by the ACC.

3. For applicants proposing to expand their existing diagnostic cardiac catheterization service to also provide therapeutic cardiac catheterization services on a two (2) year trial basis:

a. The applicant shall be an existing acute care hospital;

b. The applicant must have performed, according to the most recent editions of the *Kentucky Annual Administrative Claims Data Report*, an average of at least eight

hundred (800) annual diagnostic cardiac catheterization procedures during the previous two (2) years;

c. The applicant must demonstrate, based on patient transfers, that the facility will perform at least thirty six (36) primary PCI procedures per year by the end of the second year of operation;

d. The applicant's primary PCI services will be available on a continuous twenty four (24) hour per day basis;

e. The applicant's staff involved in providing PCI, including interventional cardiologists, nurses and technicians must have a current ACLS certification;

f. The applicant's catheterization laboratory must be optimally equipped;

g. The applicant must establish an ongoing program of outcomes analysis and formalized periodic case review;

h. The applicant shall have an agreement with an ACLS-capable ambulance service stating that the service will respond to a call from that facility in no greater than thirty (30) minutes and meet all ACC requirements for transporting heart patients and provide evidence that EMS or air transport has the capability to transport a patient with a balloon pump;

i. There must be an image transfer system in place between the applicant's hospital and the backup cardiac surgical facility with capabilities for immediate consultation between the applicant's cardiologist and the surgical facility's cardiothoracic surgeon or interventional cardiologist;

j. The applicant's program director must have performed at least five hundred (500) life time PCI procedures and be board certified by the American Board of Internal Medicine in interventional cardiology;

k. The applicant must participate in the American ACC-NCDR quality measurement program; and

l. The application shall contain a current, signed collaboration agreement with a tertiary hospital that has an active comprehensive cardiac surgical program (including open heart surgery) within the facility. This agreement shall commit the tertiary hospital to the following actions:

    i. Provide continuous twenty four (24) hours per day availability of consultation to the physician and nursing staff of the applicant's participating hospital in the care of patients that are candidates for and/or have received primary angioplasty;

ii. Develop and participate in a joint performance improvement program, with the participant hospital, which includes all disciplines (i.e., physicians, nurses and technicians from the staffs of both the applicant's participating hospital and the collaborating tertiary hospital) providing patient care and focuses on patient outcomes;

iii. Develop and participate in joint in-service education programs for all staff (including physicians, nurses and technicians) at the collaborating hospital. The in-service education programs will be based upon needs identified in the processes of staff evaluation and the performance improvement program; and

iv. Collaborate with the applicant's participating hospital to undergo peer review of the first one hundred and fifty (150) therapeutic cardiac catheterization procedures in collaboration with the tertiary hospital through the Joint Performance Improvement Committee. A peer review shall be conducted for all patients who were either transferred to the tertiary hospital or experienced an adverse outcome as defined by the ACC.

4. For applicants proposing to provide comprehensive (diagnostic and therapeutic) cardiac catheterization services the facility shall have an existing comprehensive cardiac surgical program (including open-heart surgery) within the facility or have met the following criteria:

a. The applicant was previously approved to expand their existing diagnostic cardiac catheterization service to also provide either primary (emergency) angioplasty services or comprehensive cardiac catheterization services on a two (2) year trial basis;

b. The applicant documents that an outside consultant, selected by the Cabinet verifies the quality of the applicant's cardiac catheterization program's risk-adjusted statistics are comparable to those reported in contemporary national data registries and also concluded their outcomes are within two (2) standard deviations of the national means for both years of the trial; and

c. The applicant projects to demonstrate a minimal institutional performance activity of 200 therapeutic procedures per year in accordance with item 4 d. below, with an ideal minimum of 400 therapeutic procedures per year by the second year of operation.

d. The applicant must have performed, according to the *Kentucky Annual Administrative Claims Data Report*, an average of 300 diagnostic cardiac catheterization procedures during the previous two (2) years and must

demonstrate an unmet need for at least 200 additional therapeutic procedures in the planning area according to the following formula:

i. The total projected number of procedures in the planning area shall be derived by multiplying the Kentucky adult therapeutic cardiac catheterization use rate by the projected adult population of the planning area three years in the future from the date of the application. The statewide use rate shall be calculated as the total number of adult inpatient and outpatient therapeutic catheterization procedures performed according to the *Kentucky Annual Administrative Claims Data Report* for the most recent twelve month period divided by the Kentucky adult population during the same time period. The total number of therapeutic cardiac catheterization procedures performed on patients residing from within the planning area by existing programs located in the planning area according to the most recent edition of the *Kentucky Annual Administrative Claims Data Report* shall be subtracted from the total projected therapeutic cardiac catheterization procedures for the planning area. If there are approved but not operational laboratories in the planning area, 200 procedures shall be subtracted from the total projected procedures for each approved, non-operational lab.

ii. The applicant shall demonstrate that they will provide at least 200 therapeutic procedures (both primary and elective) by the second year of operation and annually thereafter; and

iii. The applicant shall demonstrate that approval of a new program will not reduce the volume of therapeutic procedures performed at each existing program within the planning area, to fall below 200 therapeutic procedures annually.

5. For applicants proposing mobile adult diagnostic cardiac catheterization services only:

a. According to the most recent edition of the *Kentucky Annual Administrative Claims Data Report*, each existing fixed-site diagnostic laboratory located within fifty (50) highway miles of the proposed laboratory shall have performed at least two hundred and fifty (250) diagnostic procedures in the last twelve (12) month reporting period. Each existing comprehensive laboratory (diagnostic and therapeutic) within fifty (50) highway miles of the proposed laboratory shall have performed at least five hundred and fifty (550) procedures in the last twelve (12) month reporting period. Each existing mobile diagnostic cardiac catheterization service located within fifty (50) highway miles of the proposed laboratory shall have performed at that location a number of procedures based on the ratio of hours in operation at that location in proportion to the required two hundred and fifty (250) diagnostic procedures annually;

b. There is not a newly approved cardiac catheterization laboratory in the service area which was not operational as of the date of the most recently published data; and

c. There is not a newly approved cardiac catheterization laboratory in the service area that began operating subsequent to the date of the most recently published *Kentucky Annual Administrative Claims Data Report* that did not perform the number of diagnostic or comprehensive procedures as set forth in 3(a) above.

6. For applicants proposing a pediatric cardiac catheterization laboratory, the facility shall also offer a pediatric cardiac surgical program and a Level III neonatal intensive care unit.

7. No application to establish a mobile cardiac catheterization service shall be approved under this plan.

8. For all cardiac catheterization laboratories, the applicant shall maintain a utilization review program (including record keeping) relating to medical necessity, quality, mortality, morbidity, number of cardiac catheterizations that require repetition due to inability to read the data, and other considerations generally accepted as appropriate for review.

9. For all cardiac catheterization laboratories, the applicant shall document that the most recent national guidelines as established by the Ad Hoc Task Force on Cardiac Catheterization of the American College of Cardiology/American Heart Association and published in ACC/AHA Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories will be followed. This report sets guidelines for administration, space, equipment, personnel and working arrangements for diagnostic and therapeutic cardiac catheterization laboratories.

10. For a cardiac catheterization laboratory that provides therapeutic catheterizations, the applicant shall also document that:

a. Training for percutaneous transluminal coronary angioplasty (PTCA) will follow the guidelines set forth in the Bethesda Conference on Adult Cardiology Training (Journal of the American College of Cardiology, 1986; 7: 1191-218), as revised, which require extra training beyond the two years for clinical cardiology; and

b. Each physician is projected to perform at least seventy-five (75) successful angioplasties per year with acceptable mortality and morbidity in patients who warrant the procedure.

B. Magnetic Resonance Imaging Equipment

Definition

"Magnetic Resonance Imaging" ("MRI") means a diagnostic imaging modality which utilizes magnetic resonance, an interaction between atoms and electromagnetic fields, to produce images of internal body structures.

A MRI "procedure" is defined as a MRI diagnostic scan or combination of scans performed on a single patient in a single session.

"Qualified Academic Medical Center" means each:
(a) Institution of higher education which operates an accredited medical school in the Commonwealth of Kentucky,
(b) Institution, organization or other entity which directly or indirectly owns or is under common control or ownership with such an accredited medical school, and
(c) Organization or other person which is qualified under Section 501(c)(3) of the Internal Revenue Code as a result of supporting or operating in support of any institution, organization or other person of a type or types referenced in part (a) or (b) of this sentence.

Review Criteria

An application to establish a MRI service shall be consistent with this Plan if the following criteria are met:

1. An applicant proposing to provide fixed-site MRI services shall demonstrate that sufficient need exists for that unit to perform a minimum of two thousand, five hundred (2,500) procedures per year by the end of the second year of operation;

2. An applicant proposing to provide mobile MRI services shall demonstrate that sufficient need exists for that unit to perform a minimum of one thousand, eight hundred-fifty (1,850) procedures, within the Commonwealth, per year by the end of the second year of operation;

3. Notwithstanding criteria 1, 2 or 5, an application to establish MRI services shall be consistent with this Plan if:

    a. The proposed unit would be used under formalized, written agreements with a qualified academic medical center and that as a result of teaching services provided there would be additional time spent with each patient during the performance of the MRI procedure which would prevent the provider from performing the requisite minimum number of procedures for that type of MRI unit;

    b. The proposed unit would be used solely for pediatric patients or patients that require full sedation in order for the procedure to be performed; or

c. The proposed unit would be used primarily during intraoperative procedures.

4. The applicant shall certify and be capable of demonstrating that the proposed equipment to be used in conjunction with the procedures is safe and effective including the following:

   a. The United States Food and Drug Administration (FDA) has certified the proposed equipment for clinical use;

   b. The physical setting at which the procedures are to be performed conforms to applicable federal standards, manufacturer's specifications and licensing agencies' requirements;

   c. Only qualified, trained personnel shall be allowed to operate the equipment;

   d. A licensed, board certified radiologist or other licensed physician demonstrating experience and training in the provision of MRI services shall supervise all non-employee personnel and interpret all scans performed;

   e. If the equipment is to be leased or otherwise acquired on a contractual basis, the lease or contract does not require that a specific minimum number of procedures be performed;

   f. The procedures are medically necessary and will not unnecessarily duplicate other services; and

   g. Sufficient protocols exist to address any emergencies associated with the provision of the proposed services.

5. The applicant demonstrates that its ability to provide at least two thousand, five hundred (2,500) procedures per year from a fixed-site MRI or to provide at least one thousand, eight hundred-fifty (1,850) procedures per year from a mobile MRI unit does not result in unnecessary duplication of services. Specifically, the applicant must demonstrate that the procedures it proposes to perform would be in addition to the lesser of:

   a. The procedures performed by each existing licensed provider in the proposed county as reported in the most recent edition of the *Kentucky Annual Magnetic Resonance Imaging Services Report*;

   b. Two thousand, five hundred (2,500) procedures per year by each existing certificate of need approved or licensed fixed-site MRI provider in the proposed county; or

   c. One thousand, eight hundred-fifty (1,850) procedures per year by each existing certificate of need approved or licensed mobile MRI provider in the proposed county.

6. Notwithstanding criterion 1, 2, 3 & 5, applications proposing to establish MRI services shall be considered consistent with this Plan if the applicant is an existing licensed acute care hospital that is not providing MRI services at its existing campus. The establishment of such services is limited to the applicant's existing hospital campus.

C. Megavoltage Radiation Equipment

Definition

"Megavoltage Radiation Equipment" is used in the treatment of cancer. For the purposes of this plan, megavoltage radiation equipment includes units such as linear accelerators that operate at two or more megavolts and deliver external radiation.

A "Megavoltage Radiation Therapy Program" is defined as a licensed or certificate of need approved service utilizing one or more megavoltage radiation units at a single location by a single owner.

With regard to megavoltage radiation equipment, the "Planning Area" shall be comprised of the county of the proposed megavoltage radiation therapy program and all contiguous counties.

Review Criteria

An application for megavoltage radiation therapy services shall be consistent with this Plan if the following criteria are met:

1. a. The number of procedures performed in the proposed planning area averages at least eight thousand (8,000) per existing megavoltage radiation therapy program, as reported in the latest edition of the *Kentucky Annual Megavoltage Radiation Services Report*; and

   b. The applicant shall demonstrate that sufficient need exists for that program to perform a minimum of six thousand (6,000) annual procedures by the end of the second year of operation~~;~~. ~~and~~

   ~~c. Approval of the application does not cause the number of megavoltage radiation therapy programs to exceed one (1) per one hundred thousand (100,000) population in the proposed planning area; or~~

2. Notwithstanding the above criteria, an application proposing to establish a megavoltage radiation therapy program limited to image-guided robotic linear accelerator-based stereotactic radiosurgery shall be required to demonstrate only that sufficient need exists for that program to perform a minimum of one thousand (1,000) annual procedures by the end of the second year of operation~~, and further, approval under this criterion 4 shall not be included in the program-to-population ratio set forth above in criterion 3~~.

D. Positron Emission Tomography Equipment

Definition

"Positron Emission Tomography" (PET) scans combine nuclear scanning with chemical analysis to enable physicians to observe how organs work. Positrons are positively charged electrons that are produced spontaneously as certain radioactive substances (for example, radioactive glucose) decompose. The type of radioactive substance used for a particular PET scan varies, based on the medical condition for which a patient is being tested. During a PET scan, the radioactive material is introduced into the patient's body (usually by injection) and is detected by a sophisticated camera that obtains sectional views through a patient's body.

A "PET Procedure" is defined as a PET diagnostic scan or combination of scans performed on a single patient in a single session.

A "PET Program" is defined as a licensed or certificate of need approved service utilizing one or more PET units at a single location by a single owner.

A "mobile PET Scanner" means a PET scanner and transporting equipment that is moved to provide services at two or more host facilities.

With regard to PET equipment, the "Planning Area" shall be comprised of the county of the proposed PET program and all contiguous counties.

Review Criteria

An application for PET services shall be consistent with this Plan if the following criteria are met:

1. Applicants proposing to establish a fixed-site PET unit must project a minimum of at least nine hundred (900) procedures in the first full year of operation and one thousand, two hundred (1,200) procedures per year by the second full year of service and annually thereafter;

2. Applicants proposing to establish or expand a mobile PET service must project a minimum of at least five hundred-forty (540) mobile procedures within the Commonwealth in the first full year of service and at least seven hundred-twenty (720) procedures within the Commonwealth per year by the second full year of service and annually thereafter;

3. The application shall document a projection of need for the PET unit which shall include demographic patterns, including analysis of applicable population-based health status factors, estimated utilization by patient clinical diagnoses category (ICD-9), and documentation demonstrating that the applicant is providing or has referral arrangements with other medical providers that offer comprehensive cancer and cardiac diagnostic and treatment services; and

4. Approval of the application does not cause the number of licensed or certificate of need approved fixed-site PET programs to exceed one (1) per one hundred-thousand (100,000) population in the proposed planning area.

E. New Technology

Definition

"New Technology" includes new technological equipment or services not previously provided in the Commonwealth and not otherwise covered in the Plan that involve a capital expenditure that exceeds the capital expenditure minimum or equipment that exceeds major medical equipment minimum, and has an annual operating cost greater than $500,000, or new technology where the medical literature indicates that certain utilization levels or procedural volumes are necessary to achieve desirable patient outcomes.

Review Criteria

An application for new technology shall be consistent with the Plan if the following criteria are met:

1. The applicant shall document that the proposed new technology is efficacious;

2. The applicant shall document that the equipment is certified for its proposed use by the United States Food and Drug Administration (FDA);

3. Preference shall be given to proposals that involve multi-institutional arrangements by contract, agreement, ownership, or other means between two (2) or more agencies to coordinate services, share support services, or provide services on a geographically integrated basis. A party to a multi-institutional arrangement shall not establish its own service or participate in another arrangement for the service until the original service is operating at sufficient capacity for adequate efficiency and quality of care. If the projected use of the new service includes expected referrals from others, the referring parties should be included in the multi-institutional arrangement, if possible;

4. Preference shall be given to proposals that place the new technology in a medical school or other teaching or research facility. New technology designed for pediatric use or proposed for use by pediatric patients shall be approved only in pediatric teaching facilities which have the availability of physician specialty support and specialized ancillary support services;

5. Before acquiring new technological equipment, applicants shall have complementary diagnostic and treatment services available to support the new program;

6. In cases where specific professional standards have not yet been formulated, applicants shall demonstrate that personnel who will staff the new technology are qualified and adequately trained. The applicant shall specify how personnel will be trained in the use of the specific equipment and safety procedures to follow in the event of an emergency. The institution providing the new services shall document its plan for providing continuing education for referring physicians and institutions in the use of the new technology; and

7. Applicants acquiring new technological equipment shall report utilization and demographic data necessary to evaluate the technology and to facilitate state planning.

V. Miscellaneous Services

A. Ambulance Service

Definition

An "Ambulance Service" includes Class I, II, ~~or~~ III, or VI ground ambulances. Class I ground ambulance services provide basic life support or advanced life support services to all patients for both emergencies and scheduled ambulance transportation which is medically necessary. Class II ground ambulance services provide only basic life support services but do not provide initial response to the general population with medical emergencies and which are limited to providing scheduled ambulance transportation which is medically necessary. Class III ground ambulance services provide mobile intensive care services at or above the level of advanced life support to patients with critical illnesses or injuries who must be transported between hospitals in vehicles with specialized equipment as an extension of hospital-level care. Class VI are those services that provide advanced life support (ALS) medical first response without patient transport. These ambulance classes are set forth in KRS311A.030.

Review Criteria

An application for ground ambulance services shall be consistent with this Plan if the following criteria are met:

1. The applicant shall document that the appropriate local legislative body (fiscal court, city council, or both when applicable) has been given notice of the applicant's intent to obtain a certificate of need. Such notice shall describe the scope of service and proposed service area. For purposes of this requirement, the term "appropriate local legislative body" refers only to those legislative bodies that are currently licensed to provide ambulance services in the applicant's proposed service area;

2. In the event of competing applications to add services in the same service area, preference shall be given to an application proposing the higher level of service. If multiple providers propose ALS services, then preference shall be given to the applicant who most thoroughly documents need for the service and presents ability to meet the need; and

3. Applications to provide only Class II or Class III services shall be accompanied by documentation (e.g., charts depicting response times of existing service, number of runs during the previous year, and comparable supportive data) that the need for scheduled or critical care inter-facility transportation is not being met by the existing emergency or other Class II or III ground ambulance services. In the presence of such evidence, priority shall be given to a competing application~~s~~, if any, for the addition of vehicles, expansion of service areas, or comparable modifications that would allow an existing emergency ambulance service provider~~s~~ to meet any unmet need for critical care interfacility or scheduled ambulance services.

B. Ambulatory Surgical Center

Definition

An "Ambulatory Surgery Center" ("ASC") is a free standing or hospital based health facility where scheduled procedures which are billed as surgical procedures, to include cystoscopy procedures, are performed, and which meet the licensure requirements of the Cabinet for Health and Family Services, Office of Inspector General.

Review Criteria

An application for outpatient surgical services which will result in the establishment of an additional licensed ASC shall be consistent with the Plan if the following criteria are met:

1. Overall inpatient and outpatient surgical utilization in hospitals and ASC's is at least eighty-five (85) percent in the planning area as computed from the most recent editions of the *Kentucky Annual Ambulatory Surgical Services Report* and the *Kentucky Annual Hospital Utilization and Services Report*. With regard to ambulatory surgical services, the planning area shall be comprised of the county of the proposal and all contiguous counties;

2. Inpatient and outpatient surgical utilization is computed using an average 2.0 hours (including cleanup time) per inpatient surgery and 1.2 hours (including cleanup time) per outpatient surgery, and 2,205 potential surgical hours per year as follows:

$$\frac{\text{(Total inpatient operations* x 2.0) + (Total outpatient operations* x 1.2)}}{\text{(Existing and Approved Hospital Operating Rooms** + ASC Operating Rooms**) x 2,205}}$$

* Shall not include pain procedures performed in a procedure room as reported in the *Kentucky Annual Ambulatory Surgical Services Report* and the *Kentucky Annual Hospital Utilization and Services Report.*
** Shall not include Cystoscopy rooms as reported in the *Kentucky Annual Ambulatory Surgical Services Report* and the *Kentucky Annual Hospital Utilization and Services Report.*

Applicants proposing outpatient surgical services may use actual documented surgical time to calculate institution-specific utilization rates. Outpatient operations are the sum of all hospital outpatient and ambulatory surgical center operations;

3. All new ASC's shall be located within twenty (20) minutes normal driving time of at least one (1) acute care hospital and the applicant shall have a transfer agreement for the proposed center in place with at least one (1) acute care hospital which is located within twenty (20) minutes normal driving time of the center; and

4. Overall surgical utilization in the planning area notwithstanding, an application to establish an ASC limited to a specific type of procedure shall be consistent with this Plan if the following conditions are met:

a. The applicant documents that patients are not receiving the specific type of surgical procedures (as identified by procedure codes) proposed by the applicant at facilities in the planning area; and

b. The application contains an explanation of why the unmet need for the specific type of surgical procedure has not been reasonably addressed by providers in the planning area.

C. Chemical Dependency Treatment Beds

Definition

"Chemical dependency" treatment beds are licensed beds used in the treatment of patients suffering from abuse or addiction to chemical substances such as alcohol or drugs.

Review Criteria

An application for chemical dependency treatment beds shall be consistent with this Plan if the following criteria are met:

1. The number of chemical dependency treatment beds in an ADD shall not exceed a maximum rate of 11.4 beds per 100,000 geographic population for the plan year;

2. Consideration shall be given to the availability of acute care or psychiatric beds designated for use as chemical dependency treatment beds, as well as the availability of KRS Chapter 222 program beds;

3. Applications to develop hospital-based units using existing space shall be given priority over applications requiring new construction;

4. In ADDs with a rate below the maximum for chemical dependency treatment beds, all or a portion of the bed quota for contiguous ADDs may be used if the applicant demonstrates that:

    a. The proposed facility will be available and accessible to the population or a portion of the population of the contiguous ADDs;

    b. Linkage agreements have been made with appropriate providers in the contiguous ADDs; and

    c. Letters of support have been obtained from any licensed chemical dependency treatment providers in the contiguous ADD.

D. Outpatient Health Care Center

Definition

An "Outpatient Health Care Center" is a public or private provider-based institution with permanent facilities on a single campus, that is under the supervision of an organized medical staff and that is comprised of components for the provision of primary care, ambulatory surgery, twenty-four (24) hour emergency care, and radiologic and magnetic resonance imaging.

Review Criteria

An application for a certificate of need to establish an Outpatient Health Care Center shall be consistent with this Plan if the health facility:

1. Shall provide primary care services, twenty-four (24) hour emergency services, diagnostic imaging including magnetic resonance imaging services, ambulatory surgical services, and such other outpatient services as necessary to serve the needs of the residents of a county if there are no review criteria for those other outpatient services in the state health plan; and

2. Shall be located in a county that has no hospital, that has a population of sixty thousand (60,000) or more persons, and that also is a medically underserved area as determined by the Secretary of the Federal Department for Health and Human Services.

No more than one (1) Outpatient Health Care Center that meets the criteria in Paragraphs 1 and 2 above shall be established in each county.

E. Private Duty Nursing Service

Definition

A "Private Duty Nursing Service" is an entity that provides licensed nursing care to patients in his or her home for a continuous block of time, in increments of at least four hours, in which the private duty nursing service supervises nursing care provided by agency personnel.

Review Criteria

An application to establish a private duty nursing service shall be consistent with this Plan only if the applicant:

1. Proposes to establish or expand private duty nursing services into a county that does not have a licensed or certificate of need authorized private duty nursing service provider or a licensed or certificate of need approved home health agency that offers private duty nursing services as a component of its array of services; or

2. An application submitted by an existing agency that has met the emergency circumstances provision as outlined in 900 KAR 6:080 Section 2 and has received notice from the Office of Health Policy that an emergency exists, shall be consistent with this Plan only if the application is restricted to the limited purpose of alleviating the emergency.

3. The applicant proposes to establish private duty nursing services in, or expand private duty nursing services into, a county only for the provision of such services to pediatric patients (i.e. people under age 18).

4. The applicant proposes to establish private duty nursing services in, or expand private duty nursing services into, a county only for the provision of Model II Waver services to Medicaid recipients.

VI. Attachment A

PEDIATRICS®
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Levels of Neonatal Care

COMMITTEE ON FETUS AND NEWBORN

Pediatrics; originally published online August 27, 2012;
DOI: 10.1542/peds.2012-1999

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

POLICY STATEMENT

Levels of Neonatal Care

COMMITTEE ON FETUS AND NEWBORN

KEY WORDS

neonatal intensive care, high-risk infant, regionalization, maternal and child health, health policy, very low birth weight infant, hospital newborn care services, nurseries

ABBREVIATIONS

AAP—American Academy of Pediatrics
aOR—adjusted odds ratio
CI—confidence interval
CON—certificate of need
ELBW—extremely low birth weight
TIOP—"Toward Improving the Outcome of Pregnancy"
VLBW—very low birth weight

www.pediatrics.org/cgi/doi/10.1542/peds.2012-1999

doi:10.1542/peds.2012-1999

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

abstract

FREE

Provision of risk-appropriate care for newborn infants and mothers was first proposed in 1976. This updated policy statement provides a review of data supporting evidence for a tiered provision of care and reaffirms the need for uniform, nationally applicable definitions and consistent standards of service for public health to improve neonatal outcomes. Facilities that provide hospital care for newborn infants should be classified on the basis of functional capabilities, and these facilities should be organized within a regionalized system of perinatal care. *Pediatrics* 2012;130:587–597

OBJECTIVE

This revised policy statement reviews the current status of the designation of levels of newborn care definitions in the United States, which were delineated in a 2004 policy statement by the American Academy of Pediatrics (AAP).[1] Since publication of the 2004 policy statement, new data, both nationally and internationally, have reinforced the importance of well-defined regionalized systems of perinatal care, population-based assessment of outcomes, and appropriate epidemiologic methods to adjust for risk. This revised statement updates the designations to provide (1) a basis for comparison of health outcomes, resource use, and health care costs, (2) standardized nomenclature for public health, (3) uniform definitions for pediatricians and other health care professionals providing neonatal care, and (4) a foundation for consistent standards of service by institutions; state health departments; and state, regional, and national organizations focused on the improvement of perinatal care.

BACKGROUND

The availability of neonatal intensive care has improved the outcomes of high-risk infants born either preterm or with serious medical or surgical conditions.[2–4] Many of these improvements can be attributed to the concept and implementation of regionalized systems of perinatal care, broadly articulated in the 1976 March of Dimes report "Toward Improving the Outcome of Pregnancy" (TIOP I).[5] The TIOP I report included criteria that stratified maternal and neonatal care into 3 levels of complexity and recommended referral of high-risk patients to higher-level centers with the appropriate resources and personnel to address the required increased complexity of care. However, since the initial TIOP I report was published more than 3 decades ago, there have been signs of deregionalization, including (1)

an increase in the number of NICUs and neonatologists, without a consistent relationship to the percentage of high-risk infants, (2) a proliferation of small NICUs in the same regions as large NICUs,[6–11] and (3) failure of states to reach the Healthy People 2010 goal that 90% of deliveries of very low birth weight (VLBW; <1500 g) infants occur at level III facilities.[12,13]

In the environment of deregionalization, preterm birth rates have increased 13% overall from 1990 to 2010 (10.6%–12.0%) as a result of a variety of factors, including increases in elective early cesarean deliveries, multiple births, advanced maternal age, and complications of pregnancy.[14–20] The majority of the increase in the preterm birth rate (>70%) is attributable to late preterm births.[21] Infants born late preterm can experience significant morbidity that may result in the need for specialized care and advanced neonatal services.[22,23] An increase in the supply of specialty staff[24,25] and availability of new neonatal therapies (eg, bubble continuous positive airway pressure), have expanded the scope of care in level II facilities.[26] Some have expressed concern that level II hospitals have expanded their scope of care without sufficient evidence of favorable outcome. Because most infant deaths in the United States occur among the most immature infants in the first few days after birth,[27,28] improvements in regionalized systems may reduce mortality among the most preterm newborn infants.

REVIEW OF THE LITERATURE ON NEONATAL LEVELS OF CARE SINCE THE 2004 AAP POLICY STATEMENT

In 2004, the AAP defined neonatal levels of care, including 3 distinct levels with subdivisions in 2 of the levels.[1] Level I centers provided basic care; level II centers provided specialty care, with further subdivisions of IIA and IIB centers; and level III centers provided subspecialty care for critically ill newborn infants with subdivisions of level IIIA, IIIB, and IIIC facilities. Data published since the 2004 statement have informed the development of the levels of care in this new policy statement.

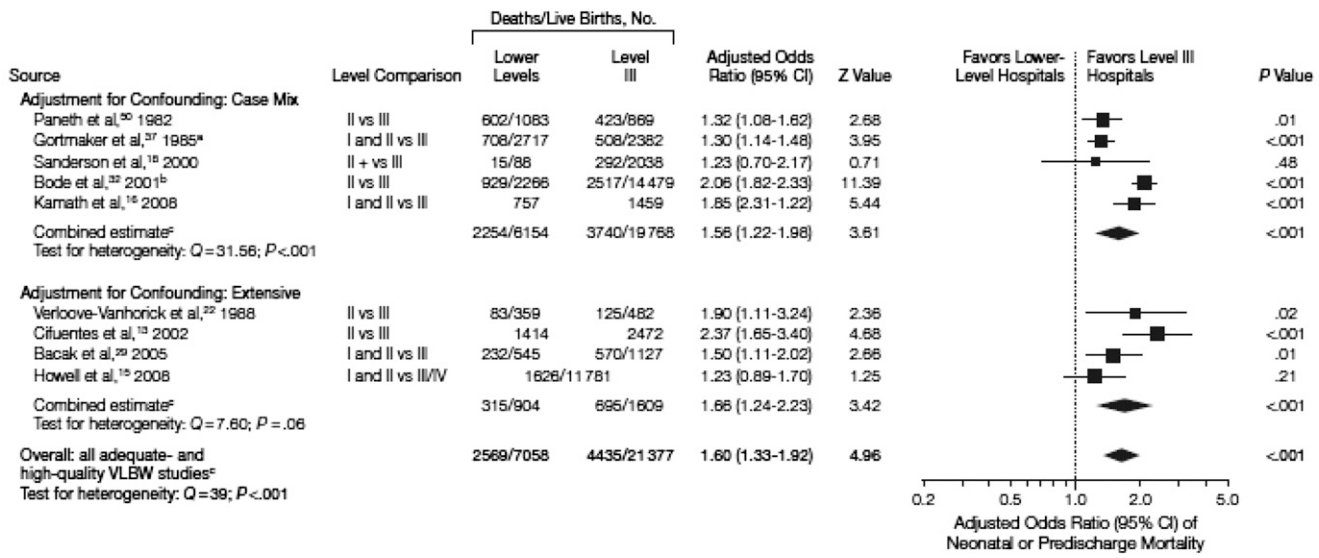
A meta-analysis of the published literature from 1978 to 2010 clearly demonstrates improved outcomes for VLBW infants and infants <32 weeks' gestational age born in level III centers. Lasswell et al reviewed 41 English-language US and international studies, which included >113 000 VLBW infants and found that VLBW infants born at non–level III hospitals had a 62% increase in odds of neonatal or predischarge mortality compared with those born at level III hospitals (adjusted odds ratio [aOR], 1.62; 95% confidence interval [CI], 1.44–1.83). Subset comparisons of studies identifying infants <32 weeks' gestation and extremely low birth weight (ELBW) infants (<1000 g) demonstrated similar effects (aOR, 1.55; 95% CI, 1.21–1.98; aOR, 1.64; 95% CI, 1.14–2.36, respectively). When only higher-quality studies were included, the findings were consistent (VLBW aOR, 1.60; 95% CI, 1.33–1.92; <32 weeks' gestation aOR, 1.42; 95% CI, 1.06–1.88; ELBW aOR, 1.80; 95% CI, 1.31–2.36). The effect of level of care on VLBW mortality did not vary by decade of publication[29]; hence, the risk of death for VLBW infants born in level I or II facilities remained higher than those born within a level III facility. Figures 1, 2, and 3 summarize the findings of these studies.

As Lasswell and colleagues found, part of the difficulty in collecting evidence to provide accurate assessments of VLBW outcomes has been in obtaining appropriate standardized measures. Heterogeneity among studies on neonatal levels of care suggests the need for a quality standard for comparison which includes the following elements: (1) population-based studies within well-defined geographic regions, (2) clear definitions of the "intervention" or hospital level of care, and (3) appropriate adjustment for confounding factors to include maternal social and demographic risk factors, pregnancy and perinatal risks, and severity of illness at delivery.

Current Controversies in Levels of Care Designation

Although little debate exists on the need for advanced neonatal services for the most immature and surgically complex neonates, ongoing controversies exist regarding which facilities are qualified to provide these services and what is the most appropriate measure for such qualification. These issues are, in general, based on the need for comparison of facility experience (measured by patient volume or census), location (inborn/outborn deliveries, regional perinatal center, or children's hospital), or case mix (including stillbirths, delivery room deaths, and complex congenital anomalies).

Several studies have explored the topic of center experience as measured by volume or census of VLBW infants.[30–35] Phibbs et al conducted a population-based retrospective cohort study of 48 237 California VLBW infants to examine differences in neonatal mortality among NICUs with various levels of care and patient volumes. When compared with high-volume, high-level centers, the odds ratio of death was 1.19 (range, 1.04–1.37) for level IIIB, IIIC, or IIID centers with <100 annual admissions, 1.78 (range, 1.35–2.34) for level IIIA centers with 26 to 50 annual admissions, and 2.72 (range, 2.37–3.12) for level I centers with <10 annual admissions. The authors also found that the percentage of VLBW infants delivered in level IIIB, IIIC, or IIID centers decreased from 36% in 1991 to 22% in



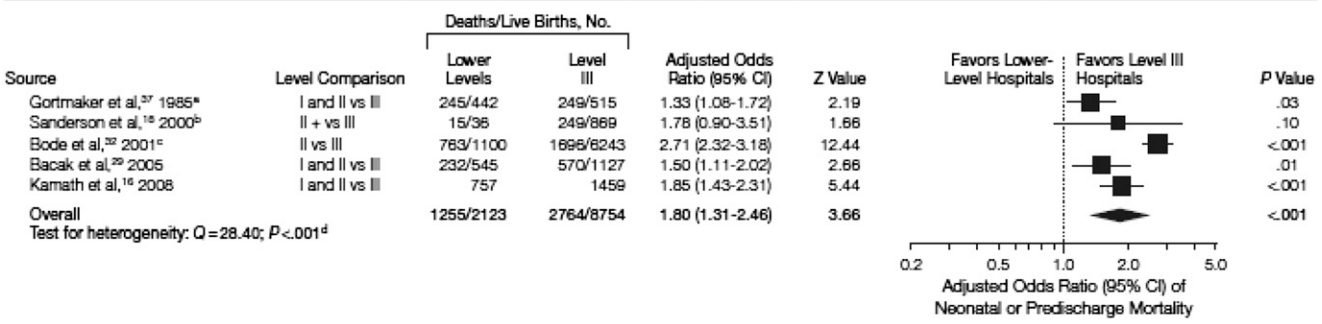
Case mix indicates adjustment for demographic and/or socioeconomic status variables; extensive indicates adjustment for case mix plus maternal/perinatal risk factors and infant illness severity. CI indicates confidence interval. Size of data markers indicates size of study population.
[a] Included data are for urban populations and combine reported black/white race strata and birth weight strata (750-1000 g and 1001-1500 g).
[b] Included data combine reported birth date interval strata (1980-1984, 1985-1989, and 1990-1994) and birth weight strata (500-1000 g and 1001-1500 g).
[c] Raw death counts are not reported in Cifuentes et al[13] and Kamath et al[16] and are not stratified by hospital level in Howell et al.[15] These studies are not included in combined death/birth counts.

FIGURE 1

Meta-analysis of adequate- and high-quality publications on VLBW infants, stratified by level of adjustment for confounding. (Reprinted with permission from Lasswell S, Barfield WD, Rochat R, Blackmon L. Perinatal regionalization for very low birth weight and very preterm infants: a meta-analysis. *JAMA.* 2010;304[9]:992–1000.[29])

2000 and estimated that shifting VLBW births in urban areas (92% of VLBW births) to level IIIC or IIID centers with >100 annual admissions would have prevented 21% of VLBW deaths in 2000.[30] In a secondary data analysis, Chung et al found that deregionalization of California perinatal services resulted in 20% of VLBW deliveries occurring in level I and level II hospitals, with lower-volume hospitals having the highest odds of mortality.[31]

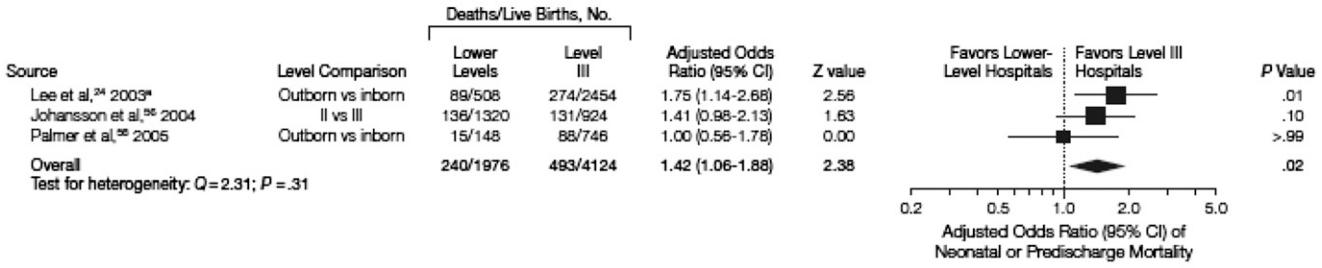
A population-based study of 4379 VLBW infants who were born between 1991 and 1999 in Lower Saxony, Germany, evaluated neonatal mortality in relation to both the annual volume of births and NICU volume.[32] There was an increased odds of mortality in centers with annual NICU admissions of fewer than 36 VLBW infants; the largest



CI indicates confidence interval. Size of data markers indicates size of study population.
[a] Included data are for urban populations and combine reported black/white race strata.
[b] Included data combine reported birth weight strata (500-749 g and 750-1000 g).
[c] Included data combine reported birth date interval strata (1980-1984, 1985-1989, and 1990-1994).
[d] The study by Kamath et al[16] does not report raw death count data and is not included in combined death/birth counts.

FIGURE 2

Meta-analysis of adequate- and high-quality publications on ELBW infants. (Reprinted with permission from Lasswell S, Barfield WD, Rochat R, Blackmon L. Perinatal regionalization for very low birth weight and very preterm infants: a meta-analysis. *JAMA.* 2010;304[9]:992–1000.[29])



CI indicates confidence interval. Size of data markers indicates size of study population. Inborn infants are those born in a level III hospital; outborn infants are those born in a lower-level hospital then transferred to a level III hospital.
[a] Included data combine reported gestational age strata (<26 weeks, 27-29 weeks, and 30-31 weeks).

FIGURE 3

Meta-analysis of adequate- and high-quality publications on very preterm infants (<32 weeks' gestation). (Reprinted with permission from Lasswell S, Barfield WD, Rochat R, Blackmon L. Perinatal regionalization for very low birth weight and very preterm infants: a meta-analysis. *JAMA*. 2010;304[9]:992–1000.[29])

effect on mortality was for infants born at less than 29 weeks' gestation.

Other studies assessing NICU volume suggest caution in using this measure as an effective indicator of quality of care. Rogowski and colleagues assessed the potential usefulness of NICU volume as a quality indicator among 94 110 VLBW infants entered into the Vermont Oxford Network database between 1995 and 2000 and compared NICU volume with other indicators based on hospital characteristics and patient outcomes.[33] They found that although annual volume explained 9% of the variation in hospital mortality rates, other hospital characteristics explained another 7%. They suggested that direct measures based on patient outcomes are more useful quality indicators than volume for the purpose of selective referral.

Several studies assessed the effects of level of care, patient volume, and racial disparities on mortality of VLBW infants based on births in minority-serving hospitals. Morales[34] and Howell[35] evaluated mortality of VLBW infants born in minority-serving hospitals. In both studies, neonatal level of care and patient volume were each independently associated with mortality, suggesting that delivery of all VLBW infants at high-volume hospitals would reduce black-white disparities in VLBW mortality rates. Rogowski and colleagues further suggest that the quality of care in poor-outcome hospitals could be improved through collaborative quality improvement, and evidence-based selective referral.[36]

Several studies have compared the short-term outcome of VLBW infants born in centers with level III units (inborn) compared with those born at lower level centers and soon transferred to a higher level (level III or children's hospital; outborn). Many of these studies are retrospective and may be subject to selection bias because infants who were transferred most likely had the highest chance of survival and thus gave the impression of lower mortality.[24] In a secondary analysis of a randomized placebo-controlled study of preemptive morphine analgesia on neonatal outcomes, Palmer et al compared neonatal mortality as related to place of birth for 894 infants who were born at 23 to 32 weeks' gestation. Outborn babies were more likely to have severe intraventricular hemorrhage ($P = .0005$), and this increased risk persisted after controlling for severity of illness. However, when adjusted for antenatal steroids, the effect of birth center was no longer significant.[37]

Evaluating and controlling for confounding variables and "case-mix" presents another set of challenges because these factors vary by population. For example, race and insurance status may have more of an effect on birth outcomes in the United States[34–36,38] than in countries with a more homogenous population and universal national health care.[39] There are also potential confounding factors for which measurement is frequently lacking, such as parental wishes regarding aggressive resuscitation of an infant. Arad et al noted that parental wishes varied by religious affiliation in their 2-hospital study. Because religious affiliation was unequally distributed between the 2 hospitals, fewer attempts at resuscitation may have been made at the level III hospital, with a result of improved survival at the level II facility.[40] More comprehensive studies controlling for confounding factors are needed.

Measured outcomes other than VLBW mortality (notably, fetal mortality, postdischarge mortality, and long-term physical and neurodevelopmental outcomes) may offer important information in assessing the evidence for newborn levels of care and perinatal regionalization. Studies measuring the effect of hospital level of birth on fetal

and neonatal outcomes stratified by gestational age, as well as by birth weight, are also helpful, because gestational age is a better gauge of fetal maturity.[41–44] Although some studies include stillbirths and intrapartum fetal deaths, measurement and surveillance of fetal death varies widely.[3] Congenital anomalies are often excluded from studies of perinatal regionalization but should be considered in the provision of risk appropriate care.[45]

Additional studies are also needed to assess the effectiveness and potential cost savings of centralizing expensive technologies and provider expertise for relatively rare conditions at a few locations and to assess the effectiveness, including costs, of antenatal transport.

IMPORTANCE OF NEONATAL LEVELS OF CARE

Provision of Standardized Nomenclature for Public Health

Since 2004, efforts have been made to improve the comparison of health outcomes by hospital facility through the use of standardized nomenclature on the US birth certificate. The National Center for Health Statistics at the Centers for Disease Control and Prevention has worked with states to use the newly revised US Standard Certificate of Birth.[46] This 2003 revised certificate defines a NICU as a "hospital facility or unit staffed and equipped to provide continuous mechanical ventilatory support for a newborn infant." It also includes information on the use of antenatal therapies and postpartum surfactant, which may be useful in monitoring population-based utilization of technologies at birth.[47] In an analysis of 16 states using the revised certificate of birth, Barfield et al found that overall, 77.3% of VLBW infants were admitted to NICUs; this estimate varied by state and ranged from 63.7% in California to 93.4% in North Dakota. Among VLBW infants of Hispanic mothers, 71.8% were admitted to NICUs, compared with 79.5% of VLBW infants of non-Hispanic black mothers and 80.5% of VLBW infants of non-Hispanic white mothers. In multivariable analysis, preterm delivery, multiple gestation, and cesarean delivery were associated with higher prevalence of NICU admission among VLBW infants.[13] State variations in the receipt of intensive care for VLBW infants may explain, in part, variation in VLBW outcomes across the country.

Use of Uniform Definitions of Levels of Care for Pediatricians and Other Health Care Professionals

Variation in definition, criteria, and state enforcement still occurs despite the TIOP I guidelines. Blackmon et al conducted an extensive review of all 50 states and the District of Columbia governmental Web sites to assess state definitions and levels terminology, functional and utilization criteria, regulatory compliance and funding measures, and citation of AAP documents on levels of neonatal care. The authors found that state definitions, criteria, compliance, and regulatory mechanisms for the specific type of care neonatal centers provide varied considerably, and they suggested a consistent national approach.[48] Lorch et al assessed all 50 states and the District of Columbia to identify state certificate of need (CON) legislation, a mechanism that regulates the expansion of NICU facilities and NICU beds. Thirty states regulated the construction of NICUs through CON programs, and non-CON program states were associated with more NICU facilities and more NICU beds (relative risk, 2.06; 95% CI, 1.74–2.45; and relative risk, 1.96; 95% CI, 1.89–2.03, respectively). In large metropolitan areas, non-CON states had higher infant mortality for all birth weight groups.[49]

The Maternal and Child Health Bureau of the Health Resources and Services Administration has worked with state Title V agencies to document the percentage of VLBW infants delivered in level III hospitals or subspecialty perinatal clinics. In 2009, only 5 states met the goal of at least 90% of VLBW infants delivered at high-risk facilities.[12] Yet, the interpretation and reporting of these facilities may be inconsistent as some states had unclear facility definitions or included level II facilities in their reporting. Recently, several states, in partnership with national organizations, have taken more definitive action in defining and regulating organization of perinatal care.[50]

Development of Consistent Standards of Service

Efforts by quality-improvement collaboratives, health services researchers, and public health officials will continue to improve the standards by which to measure quality of care.[51,52] Quality-improvement activities have begun to flourish at all levels to improve maternal and perinatal health and ideally prevent preterm births; this includes provider-level quality-improvement activities, hospital-level performance measures, and regional, state, and national performance measures.[53] Organizations such as the March of Dimes have promoted standard definitions of levels of care since the introduction of perinatal regionalization in the 1970s, reaffirmed its importance in 1993 (TIOP II),[54] and included the concept of quality care for the prevention of preterm birth with a new TIOP (TIOP III) in 2010.[53]

DEFINITIONS OF LEVELS OF NEONATAL CARE

The updated classification consists of basic care (level I), specialty care (level II), and subspecialty intensive care (level III, level IV; Table 1). These definitions reflect the overall evidence for risk-appropriate care through the availability of appropriate personnel, physical space, equipment, technology, and

TABLE 1 Definitions, Capabilities, and Provider Types: Neonatal Levels of Care

Level of Care	Capabilities	Provider Types[a]
Level I Well newborn nursery	• Provide neonatal resuscitation at every delivery • Evaluate and provide postnatal care to stable term newborn infants • Stabilize and provide care for infants born 35–37 wk gestation who remain physiologically stable • Stabilize newborn infants who are ill and those born at <35 wk gestation until transfer to a higher level of care	Pediatricians, family physicians, nurse practitioners, and other advanced practice registered nurses
Level II Special care nursery	Level I capabilities plus: • Provide care for infants born ≥32 wk gestation and weighing ≥1500 g who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis • Provide care for infants convalescing after intensive care • Provide mechanical ventilation for brief duration (<24 h) or continuous positive airway pressure or both • Stabilize infants born before 32 wk gestation and weighing less than 1500 g until transfer to a neonatal intensive care facility	Level I health care providers plus: Pediatric hospitalists, neonatologist, and neonatal nurse practitioners.
Level III NICU	Level II capabilities plus: • Provide sustained life support • Provide comprehensive care for infants born <32 wks gestation and weighing <1500 g and infants born at all gestational ages and birth weights with critical illness • Provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical specialists, pediatric anesthesiologists, and pediatric opthalmologists • Provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide • Perform advanced imaging, with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography	Level II health care providers plus: Pediatric medical subspecialists[b], pediatric anesthesiologists[b], pediatric surgeons, and pediatric opthalmologists[b].
Level IV Regional NICU	Level III capabilities plus: • Located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions • Maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the site • Facilitate transport and provide outreach education	Level III health care providers plus: Pediatric surgical subspecialists

[a] Includes all providers with relevant experience, training, and demonstrated competence.
[b] At the site or at a closely related institution by prearranged consultative agreement.

organization.[55] Each level reflects the minimal capabilities, functional criteria, and provider type required. Currently, there are 148 specialty care units and 809 subspecialty care units self-identified in the 2009 AAP perinatal section directory.

Level I

Level I facilities (well newborn nurseries) provide a basic level of care to neonates who are low risk. They have the capability to perform neonatal resuscitation at every delivery and to evaluate and provide routine postnatal care for healthy newborn infants. In addition, they can care for preterm infants at 35 to 37 weeks' gestation who are physiologically stable and can stabilize newborn infants who are less than 35 weeks of gestation or who are ill until they can be transferred to a facility at which specialty neonatal care is provided. Because late preterm infants (34–36 weeks' gestation) are at risk for increased neonatal morbidity and mortality, more evidence is needed to determine their outcomes by level of care.

Level II

Care in a specialty-level facility (level II) should be reserved for stable or

moderately ill newborn infants who are born at ≥32 weeks' gestation or who weigh ≥1500 g at birth with problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty-level services on an urgent basis. These situations usually occur as a result of relatively uncomplicated preterm labor or preterm rupture of membranes. There is limited evidence to support the specific subdivision of level II care, in part because of the lack of studies with well-defined subdivisions. Level II facilities should take into consideration geographic constraints and population size when assessing the staffing resources needed to care appropriately for moderately ill newborn infants.

Level II nurseries may provide assisted ventilation on an interim basis until the infant's condition either soon improves or the infant can be transferred to a higher-level facility. Delivery of continuous positive airway pressure should be readily available by experienced personnel, and mechanical ventilation can be provided for a brief duration (less than 24 hours). Level II nurseries must have equipment (eg, portable x-ray machine, blood gas analyzer) and personnel (eg, physicians, specialized nurses, respiratory therapists, radiology technicians, laboratory technicians) continuously available to provide ongoing care as well as to address emergencies. Referral to a higher level of care should occur for all infants when needed for pediatric surgical or medical subspecialty intervention.

Level III

Evidence suggests that infants who are born at <32 weeks' gestation, weigh <1500 g at birth, or have medical or surgical conditions, regardless of gestational age, should be cared for at a level III facility. Designation of level III care should be based on clinical experience, as demonstrated by large patient volume, increasing complexity of care, and availability of pediatric medical subspecialists and pediatric surgical specialists. Subspecialty care services should include expertise in neonatology and also ideally maternal-fetal medicine, if mothers are referred for the management of potential preterm birth. Level III NICUs are defined by having continuously available personnel (neonatologists, neonatal nurses, respiratory therapists) and equipment to provide life support for as long as necessary. Facilities should have advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition and pharmacy support with pediatric expertise, social services, and pastoral care.

Level III facilities should be able to provide ongoing assisted ventilation for 24 hours or more, which may include conventional ventilation, high-frequency ventilation, and inhaled nitric oxide. Level III facility capabilities should also be based on a region's consideration of geographic constraints, population size, and personnel resources. If geographic constraints for land transportation exist, the level III facility should ensure availability of rotor and fixed-wing transport services to quickly and safely transfer infants requiring subspecialty intervention.[56] Potential transfer to higher-level facilities or children's hospitals, as well as back-transport of recovering infants to lower-level facilities, should be considered as clinically indicated.

A broad range of pediatric medical subspecialists and pediatric surgical specialists should be readily accessible on site or by prearranged consultative agreements. Prearranged consultative agreements can be performed by using telemedicine technology and/or telephone consultation, for example, from a distant location.[50] Pediatric ophthalmology services and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity should be readily available in level III facilities.[57] Level III units should have the capability to perform major surgery on site or at a closely related institution, ideally in close geographic proximity. Because the outcomes of less complex surgical procedures in children, such as appendectomy or pyloromyotomy, are better when performed by pediatric surgeons compared with general surgeons, it is recommended that pediatric surgical specialists (including anesthesiologists with pediatric expertise) perform all procedures in newborn infants.[58]

Level III facilities should have the capability to perform advanced imaging with interpretation on an urgent basis, including CT, MRI, and echocardiography. Level III facilities should collect data to assess outcomes within their facility and to compare with other levels.

Level IV

Level IV units include the capabilities of level III with additional capabilities and considerable experience in the care of the most complex and critically ill newborn infants and should have pediatric medical and pediatric surgical specialty consultants continuously available 24 hours a day. Level IV facilities would also include the capability for surgical repair of complex conditions (eg, congenital cardiac malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation). More evidence is needed to assess the risk of morbidity and mortality by level of care for newborn infants with complex congenital cardiac malformations. A recent study by Burstein et al[59] was not able to note a difference in postoperative morbidity or mortality

associated with dedicated pediatric cardiac ICUs versus NICUs and PICUs but did not separately assess the newborn and postneonatal periods. Although specific supporting data are not currently available, it is thought that concentrating the care of such infants at designated level IV centers will allow these centers to develop the expertise needed to achieve optimal outcomes.

Not all level IV hospitals need to act as regional centers; however, regional organization of perinatal health care services requires that there be coordination in the development of specialized services, professional continuing education to maintain competency, facilitation of opportunities for transport and back-transport,[60] and collection of data on long-term outcomes to evaluate both the effectiveness of delivery of perinatal health care services and the safety and efficacy of new therapies. These functions usually are best achieved when responsibility is concentrated in a single regional center with both perinatal and neonatal subspecialty services. In some cases, regional coordination may be provided adequately by the collaboration of a children's hospital with a subspecialty perinatal facility that is in close geographic proximity.[61]

STANDARDS OF SERVICE FOR HOSPITALS PROVIDING NEONATAL CARE

Current evidence indicates that family and cultural considerations are important for care of sick neonates.[62–65] These considerations include family- and patient-centered care, culturally effective care, family-based education, and opportunities for back-transport to level II facilities or transfer to the family's local community facility when medically and socially indicated.[64–67]

SUMMARY AND RECOMMENDATIONS

1. Regionalized systems of perinatal care are recommended to ensure that each newborn infant is delivered and cared for in a facility most appropriate for his or her health care needs, when possible, and to facilitate the achievement of optimal health outcomes.
    - Because VLBW and/or very preterm infants are at increased risk of predischarge mortality when born outside of a level III center, they should be delivered at a level III facility unless this is precluded by the mother's medical condition or geographic constraints.
2. The functional capabilities of facilities that provide inpatient care for newborn infants should be classified uniformly on the basis of geographic and population parameters in collaboration with state health departments, as follows:
    - Level I: a hospital nursery organized with the personnel and equipment to perform neonatal resuscitation, evaluate and provide postnatal care of healthy newborn infants, provide care for infants born at 35 to 37 weeks' gestation who remain physiologically stable, and stabilize ill newborn infants or infants born at less than 35 weeks' gestational age until transfer to a facility that can provide the appropriate level of neonatal care.
    - Level II: a hospital special care nursery organized with the personnel and equipment to provide care to infants born at 32 weeks' gestation or more and weighing 1500 g or more at birth who have physiologic immaturity, such as apnea of prematurity, inability to maintain body temperature, or inability to take oral feedings; who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis; or who are convalescing from a higher level of intensive care. A level II center has the capability to provide continuous positive airway pressure and may provide mechanical ventilation for brief durations (less than 24 hours).
    - Level III: a hospital NICU organized with personnel and equipment to provide continuous life support and comprehensive care for extremely high-risk newborn infants and those with critical illness. This includes infants born weighing <1500 g or at <32 weeks' gestation. Level III units have the capability to provide critical medical and surgical care. Level III units routinely provide ongoing assisted ventilation; have ready access to a full range of pediatric medical subspecialists; have advanced imaging with interpretation on an urgent basis, including CT, MRI, and echocardiography; have access to pediatric ophthalmologic services with an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity; and have pediatric surgical specialists and pediatric anesthesiologists on site or at a closely related institution to perform major surgery. Level III units can facilitate transfer to higher-level facilities or children's hospitals, as well as back-transport recovering infants to lower-level facilities, as clinically indicated.
    - Level IV units have the capabilities of a level III NICU and

are located within institutions that can provide on-site surgical repair of serious congenital or acquired malformations. Level IV units can facilitate transport systems and provide outreach education within their catchment area.

3. The functional capabilities of facilities that provide inpatient care for newborn infants should be classified uniformly and with clear definitions that include requirements for equipment, personnel, facilities, ancillary services, training, and the organization of services (including transport) for the capabilities of each level of care.
4. Population-based data on patient outcomes, including mortality, morbidity, and long-term outcomes, should be obtained to provide level-specific standards for patients requiring various categories of specialized care, including surgery.

LEAD AUTHOR

CAPT Wanda Denise Barfield, MD, MPH

COMMITTEE ON FETUS AND NEWBORN, 2011–2012

Lu-Ann Papile, MD, Chairperson
Jill E. Baley, MD
William Benitz, MD
James Cummings, MD
Waldemar A. Carlo, MD
Praveen Kumar, MD
Richard A. Polin, MD
Rosemarie C. Tan, MD, PhD
Kristi L. Watterberg, MD

LIAISONS

CAPT Wanda Denise Barfield, MD, MPH – *Centers for Disease Control and Prevention*
George Macones, MD – *American College of Obstetricians and Gynecologists*
Ann L. Jefferies, MD – *Canadian Pediatric Society*
Rosalie O. Mainous, PhD, RNC, NNP – *National Association of Neonatal Nurses*
Tonse N. K. Raju, MD, DCH – *National Institutes of Health*
Kasper S. Wang, MD – *Section on Surgery*

STAFF

Jim Couto, MA

REFERENCES

1. Stark AR; American Academy of Pediatrics Committee on Fetus and Newborn. Levels of neonatal care. *Pediatrics*. 2004;114(5):1341–1347
2. Bode MM, O'shea TM, Metzguer KR, Stiles AD. Perinatal regionalization and neonatal mortality in North Carolina, 1968–1994. *Am J Obstet Gynecol*. 2001;184(6):1302–1307
3. MacDorman MF, Kirmeyer S. Fetal and perinatal mortality, United States, 2005. *Natl Vital Stat Rep*. 2009;57(8):1–19
4. Clement MS. Perinatal care in Arizona 1950–2002: a study of the positive impact of technology, regionalization and the Arizona perinatal trust. *J Perinatol*. 2005;25(8):503–508
5. March of Dimes, Committee on Perinatal Health. *Toward Improving the Outcome of Pregnancy: Recommendations for the Regional Development of Maternal and Perinatal Health Services*. White Plains, NY: March of Dimes National Foundation; 1976
6. Richardson DK, Reed K, Cutler JC, et al. Perinatal regionalization versus hospital competition: the Hartford example. *Pediatrics*. 1995;96(3 pt 1):417–423
7. Yeast JD, Poskin M, Stockbauer JW, Shaffer S. Changing patterns in regionalization of perinatal care and the impact on neonatal mortality. *Am J Obstet Gynecol*. 1998;178(1 pt 1):131–135
8. Goodman DC, Fisher ES, Little GA, Stukel TA, Chang CH. Are neonatal intensive care resources located according to need? Regional variation in neonatologists, beds, and low birth weight newborns. *Pediatrics*. 2001;108(2):426–431
9. Howell EM, Richardson D, Ginsburg P, Foot B. Deregionalization of neonatal intensive care in urban areas. *Am J Public Health*. 2002;92(1):119–124
10. Haberland CA, Phibbs CS, Baker LC. Effect of opening midlevel neonatal intensive care units on the location of low birth weight births in California. *Pediatrics*. 2006;118(6). Available at: www.pediatrics.org/cgi/content/full/118/6/e1667
11. Dobrez D, Gerber S, Budetti P. Trends in perinatal regionalization and the role of managed care. *Obstet Gynecol*. 2006;108(4):839–845
12. US Department of Health and Human Services, Health Resources and Service Administration, Maternal and Child Health Bureau. National Performance Measure # 17. Available at: https://perfdata.hrsa.gov/mchb/TVISReports/. Accessed July 12, 2012
13. Centers for Disease Control and Prevention (CDC). Neonatal intensive-care unit admission of infants with very low birth weight—19 States, 2006. *MMWR Morb Mortal Wkly Rep*. 2010;59(44):1444–1447
14. Martin JA, Hamilton BE, Ventura SJ, et al. Births: final data for 2009. *Natl Vital Stat Rep*. 2011;60(1):1–70
15. Yoder BA, Gordon MC, Barth WH Jr. Late-preterm birth: does the changing obstetric paradigm alter the epidemiology of respiratory complications? *Obstet Gynecol*. 2008;111(4):814–822
16. Schieve LA, Ferre C, Peterson HB, Macaluso M, Reynolds MA, Wright VC. Perinatal outcome among singleton infants conceived through assisted reproductive technology in the United States. *Obstet Gynecol*. 2004;103(6):1144–1153
17. Joseph KS, Marcoux S, Ohlsson A, et al; Fetal and Infant Heath Study Group of the Canadian Perinatal Surveillance System. Changes in stillbirth and infant mortality associated with increases in preterm birth among twins. *Pediatrics*. 2001;108(5):1055–1061
18. Kaaja RJ, Greer IA. Manifestations of chronic disease during pregnancy. *JAMA*. 2005;294(21):2751–2757
19. Shapiro-Mendoza CK, Tomashek KM, Kotelchuck M, et al. Effect of late-preterm birth and maternal medical conditions on newborn morbidity risk. *Pediatrics*. 2008;121(2). Available at: www.pediatrics.org/cgi/content/full/121/2/e223
20. Yang Q, Greenland S, Flanders WD. Associations of maternal age- and parity-related factors with trends in low-birthweight rates: United States, 1980 through 2000. *Am J Public Health*. 2006;96(5):856–861
21. Davidoff MJ, Dias T, Damus K, et al. Changes in the gestational age distribution among U.S. singleton births: impact on rates of late preterm birth, 1992 to 2002. *Semin Perinatol*. 2006;30(1):8–15
22. Engle WA, Tomashek KM, Wallman C; Committee on Fetus and Newborn, American

Academy of Pediatrics. "Late-preterm" infants: a population at risk. *Pediatrics*. 2007;120(6):1390–1401

23. Ramachandrappa A, Rosenberg ES, Wagoner S, Jain L. Morbidity and mortality in late preterm infants with severe hypoxic respiratory failure on extra-corporeal membrane oxygenation. *J Pediatr*. 2011;159(2):192–198, e3
24. Philip AG. The evolution of neonatology. *Pediatr Res*. 2005;58(4):799–815
25. Thompson LA, Goodman DC, Little GA. Is more neonatal intensive care always better? Insights from a cross-national comparison of reproductive care. *Pediatrics*. 2002;109(6):1036–1043
26. Gould JB, Marks AR, Chavez G. Expansion of community-based perinatal care in California. *J Perinatol*. 2002;22(8):630–640
27. Stoll BJ, Hansen NI, Bell EF, et al; Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Neonatal outcomes of extremely preterm infants from the NICHD Neonatal Research Network. *Pediatrics*. 2010;126(3):443–456
28. Heron M, Sutton PD, Xu J, Ventura SJ, Strobino DM, Guyer B. Annual summary of vital statistics: 2007. *Pediatrics*. 2010;125(1):4–15
29. Lasswell SM, Barfield WD, Rochat RW, Blackmon L. Perinatal regionalization for very low-birth-weight and very preterm infants: a meta-analysis. *JAMA*. 2010;304(9):992–1000
30. Phibbs CS, Baker LC, Caughey AB, Danielsen B, Schmitt SK, Phibbs RH. Level and volume of neonatal intensive care and mortality in very-low-birth-weight infants. *N Engl J Med*. 2007;356(21):2165–2175
31. Chung JH, Phibbs CS, Boscardin WJ, Kominski GF, Ortega AN, Needleman J. The effect of neonatal intensive care level and hospital volume on mortality of very low birth weight infants. *Med Care*. 2010;48(7):635–644
32. Bartels DB, Wypij D, Wenzlaff P, Dammann O, Poets CF. Hospital volume and neonatal mortality among very low birth weight infants. *Pediatrics*. 2006;117(6):2206–2214
33. Rogowski JA, Horbar JD, Staiger DO, Kenny M, Carpenter J, Geppert J. Indirect vs direct hospital quality indicators for very low-birth-weight infants. *JAMA*. 2004;291(2):202–209
34. Morales LS, Staiger D, Horbar JD, et al. Mortality among very low-birthweight infants in hospitals serving minority populations. *Am J Public Health*. 2005;95(12):2206–2212
35. Howell EA, Hebert P, Chatterjee S, Kleinman LC, Chassin MR. Black/white differences in very low birth weight neonatal mortality rates among New York City hospitals. *Pediatrics*. 2008;121(3). Available at: www.pediatrics.org/cgi/content/full/121/3/e407
36. Rogowski JA, Staiger DO, Horbar JD. Variations in the quality of care for very-low-birthweight infants: implications for policy. *Health Aff (Millwood)*. 2004;23(5):88–97
37. Palmer KG, Kronsberg SS, Barton BA, Hobbs CA, Hall RW, Anand KJ. Effect of inborn versus outborn delivery on clinical outcomes in ventilated preterm neonates: secondary results from the NEOPAIN trial. *J Perinatol*. 2005;25(4):270–275
38. Wall SN, Handler AS, Park CG. Hospital factors and nontransfer of small babies: a marker of deregionalized perinatal care? *J Perinatol*. 2004;24(6):351–359
39. Zeitlin J, Gwanfogbe CD, Delmas D, et al. Risk factors for not delivering in a level III unit before 32 weeks of gestation: results from a population-based study in Paris and surrounding districts in 2003. *Paediatr Perinat Epidemiol*. 2008;22(2):126–135
40. Arad I, Baras M, Bar-Oz B, Gofin R. Neonatal transport of very low birth weight infants in Jerusalem, revisited. *Isr Med Assoc J*. 2006;8(7):477–482
41. Institute of Medicine. *Preterm Birth: Causes, Consequences, and Prevention*. Washington, DC: National Academies Press; 2007
42. Rautava L, Lehtonen L, Peltola M, et al; PERFECT Preterm Infant Study Group. The effect of birth in secondary- or tertiary-level hospitals in Finland on mortality in very preterm infants: a birth-register study. *Pediatrics*. 2007;119(1). Available at: www.pediatrics.org/cgi/content/full/119/1/e257
43. Johansson S, Montgomery SM, Ekbom A, et al. Preterm delivery, level of care, and infant death in sweden: a population-based study. *Pediatrics*. 2004;113(5):1230–1235
44. Vieux R, Fresson J, Hascoet JM, et al; EPIPAGE Study Group. Improving perinatal regionalization by predicting neonatal intensive care requirements of preterm infants: an EPIPAGE-based cohort study. *Pediatrics*. 2006;118(1):84–90
45. Audibert F. Regionalization of perinatal care: did we forget congenital anomalies? *Ultrasound Obstet Gynecol*. 2007;29(3):247–248
46. Martin JA, Menacker F. Expanded health data from the new birth certificate, 2004. *Natl Vital Stat Rep*. 2007;55(12):1–22
47. Menacker F, Martin JA. Expanded health data from the new birth certificate, 2005. *Natl Vital Stat Rep*. 2008;56(13):1–24
48. Blackmon LR, Barfield WD, Stark AR. Hospital neonatal services in the United States: variation in definitions, criteria, and regulatory status, 2008. *J Perinatol*. 2009;29(12):788–794
49. Lorch SA, Maheshwari P, Even-Shoshan O. The impact of certificate of need programs on neonatal intensive care units. *J Perinatol*. 2012;32(1):39–44
50. Nowakowski L, Barfield WD, Kroelinger CD, et al. Assessment of state measures of risk-appropriate care for very low birth weight infants and recommendations for enhancing regionalized state systems. *Matern Child Health J*. 2012;16(1):217–227
51. Acolet D, Elbourne D, McIntosh N, et al; Confidential Enquiry Into Maternal and Child Health. Project 27/28: inquiry into quality of neonatal care and its effect on the survival of infants who were born at 27 and 28 weeks in England, Wales, and Northern Ireland. *Pediatrics*. 2005;116(6):1457–1465
52. Ohlinger J, Kantak A, Lavin JP Jr;et al. Evaluation and development of potentially better practices for perinatal and neonatal communication and collaboration. *Pediatrics*. 2006;118(suppl 2):S147–S152
53. March of Dimes. *Toward Improving the Outcome of Pregnancy III: Enhancing Perinatal Health Through Quality, Safety, and Performance Initiatives (TIOP3)*. White Plains, NY: March of Dimes Foundation; 2010
54. Committee on Perinatal Health. *Toward Improving the Outcome of Pregnancy: The 90s and Beyond*. White Plains, NY: March of Dimes Foundation; 1993
55. American Academy of Pediatrics, American College of Obstetrics and Gynecology. *Guidelines for Perinatal Care*. 6th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2007
56. American Academy of Pediatrics. *Section on Transport Medicine. Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients*. 3rd ed. Elk Grove Village, IL: American Academy of Pediatrics; 2012
57. Fierson WM; Section on Ophthalmology American Academy of Pediatrics; American Academy of Ophthalmology; American Association for Pediatric Ophthalmology and Strabismus. Screening examination of premature infants for retinopathy of prematurity. *Pediatrics*. 2006;117(2):572–576
58. Kosloske A; American Academy of Pediatrics, Surgical Advisory Panel. Guidelines for referral to pediatric surgical specialists. *Pediatrics*. 2002;110(1 pt 1):187–191; *reaffirmed in* Pediatrics. 2007;119(5):1031

59. Burstein DS, Jacobs JP, Li JS, et al. Care models and associated outcomes in congenital heart surgery. *Pediatrics*. 2011;127(6). Available at: www.pediatrics.org/cgi/content/full/127/6/e1482
60. Attar MA, Lang SW, Gates MR, Iatrow AM, Bratton SL. Back transport of neonates: effect on hospital length of stay. *J Perinatol*. 2005;25(11):731–736
61. Berry MA, Shah PS, Brouillette RT, Hellmann J. Predictors of mortality and length of stay for neonates admitted to children's hospital neonatal intensive care units. *J Perinatol*. 2008;28(4):297–302
62. American College of Obstetricians and Gynecologists. Cultural sensitivity and awareness in the delivery of health care. Committee Opinion No. 493. *Obstet Gynecol*. 2011;117(5):1258–1261
63. American College of Obstetricians and Gynecologists. Effective patient-physician communication. Committee Opinion No. 492. *Obstet Gynecol*. 2011;117(5):1254–1257
64. Tucker CM. *US Department of Health and Human Services Advisory Committee on Minority Health. Reducing Health Disparities by Promoting Patient-Centered Culturally and Linguistically Sensitive/Competent Health Care*. Rockville, MD: US Public Health Service; 2009
65. Britton CV; American Academy of Pediatrics Committee on Pediatric Workforce. Ensuring culturally effective pediatric care: implications for education and health policy. *Pediatrics*. 2004;114(6):1677–1685
66. Eichner JM, Johnson BH; Committee on Hospital Care. American Academy of Pediatrics. Family-centered care and the pediatrician's role. *Pediatrics*. 2003;112(3 pt 1):691–697
67. Kattwinkel J, Cook LJ, Nowacek G, et al. Regionalized perinatal education. *Semin Neonatol*. 2004;9(2):155–165

Levels of Neonatal Care

COMMITTEE ON FETUS AND NEWBORN

Pediatrics; originally published online August 27, 2012;
DOI: 10.1542/peds.2012-1999